MEMORANDUM

TO: Delegates and Alternate Delegates to the APhA House of Delegates
FROM: Michael D. Hogue, 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 in Nashville, 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;
- 2017-2018 APhA Policy Committee Report; and
- 2017-2018 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in any of the committee-related webinars, I encourage you to visit http://pharmacist.com/learn-about-0 to view an archived version of the webinars related to the policy topics, policy committee report, or the policy review committee report.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 from 12:00-1:30pm on February 28, 2018 and from 6:00-7:30pm on March 7. Please try to participate in one of the two webinars. 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. As stated above, if you find that you are unable to participate in one of the live webinars, an archived version will be available online soon after.

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 – Davidson Ballroom (Level 1M)
Registration for the First Session will open from 12:00pm-3:00pm on Friday, March 16, 2018. Delegate registration will be located outside of Davidson Ballroom (Level 1M) of Music City Center. Registration for the Final session will be available in the same location, from 11:00am-1:30pm on Monday, March 19, 2018. 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 **Davidson Ballroom (Level 1M)**. 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 for further information.

**Planning for the 2019 House**
It’s never too early to plan ahead! In late April, APhA will begin the policy development process for 2019. 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 Nashville, or submit the form electronically by April 6, 2018 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 2018-2019 policy development process, I encourage you to complete the committee volunteer interest form by May 30, 2018 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 2018 House of Delegates! I look forward to seeing you in Nashville! 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.

Sincerely,

Michael D. Hogue, PharmD, FAPhA, FNAP
APhA Speaker of the House of Delegates

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, Senior Administrative Manager, Policy & Governance

Online: [http://www.pharmacist.com/apha-house-delegates](http://www.pharmacist.com/apha-house-delegates)  Email: hod@aphanet.org
## FRIDAY, MARCH 16

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 pm – 3:00 pm</td>
<td>Level 1M (outside Davidson Ballroom)</td>
<td>Delegate Registration</td>
</tr>
<tr>
<td>1:00 pm – 2:30 pm</td>
<td>Room 202BC</td>
<td>APhA-APPM Delegate Caucus</td>
</tr>
<tr>
<td>1:00 pm – 2:30 pm</td>
<td>Room 208B</td>
<td>APhA-APRS Delegate Caucus</td>
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<tr>
<td>3:00 pm – 5:00 pm</td>
<td>Davidson Ballroom</td>
<td>House of Delegates – First Session (Be seated by 2:45pm)</td>
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## SATURDAY, MARCH 17

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<tbody>
<tr>
<td>1:00 pm – 2:30 pm</td>
<td>Room 209A</td>
<td>New Business Review Committee Open Hearing</td>
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## SUNDAY, MARCH 18

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<tbody>
<tr>
<td>1:00 pm – 3:00 pm</td>
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<td>Policy Committee Open Hearing</td>
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## MONDAY, MARCH 19

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<td>APhA-APRS Delegate Caucus</td>
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<td>11:00 am – 1:30 pm</td>
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</tr>
<tr>
<td>1:30 pm – 4:30 pm</td>
<td>Davidson Ballroom</td>
<td>House of Delegates – Final Session (Be seated by 1:15pm)</td>
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### HOUSE OF DELEGATES OFFICE HOURS - BOARD ROOM A

<table>
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<tr>
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<th>Time</th>
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<tbody>
<tr>
<td>Thursday, March 15</td>
<td>3:00 pm – 6:00 pm</td>
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<tr>
<td>Friday, March 16</td>
<td>7:30 am – 3:00 pm</td>
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<tr>
<td>Saturday, March 17</td>
<td>8:00 am – 3:00 pm</td>
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<tr>
<td>Sunday, March 18</td>
<td>8:00 am – 3:00 pm</td>
</tr>
<tr>
<td>Monday, March 19</td>
<td>7:30 am – 1:00 pm</td>
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### FRIDAY, MARCH 16

**House of Delegates – First Session**

<table>
<thead>
<tr>
<th>Agenda</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Call to Order</td>
</tr>
<tr>
<td>2. Review of Voting Procedures</td>
</tr>
<tr>
<td>3. Credentials Report*</td>
</tr>
<tr>
<td>4. Adoption of Agenda and Rules*</td>
</tr>
<tr>
<td>5. Introduction of Head Table</td>
</tr>
<tr>
<td>6. Report of the Speaker, APhA House of Delegates</td>
</tr>
<tr>
<td>7. APhA House Rules Review Committee Report*</td>
</tr>
<tr>
<td>8. New Business Procedure</td>
</tr>
<tr>
<td>9. Report of the Committee on Nominations*</td>
</tr>
<tr>
<td>10. Speaker-elect Candidate Introduction</td>
</tr>
<tr>
<td>11. APhA Policy Review Committee Report – (Received)</td>
</tr>
<tr>
<td>12. APhA Policy Committee Report (Received)</td>
</tr>
<tr>
<td>13. Adjourn to a Committee of the Whole for Discussion of the Policy Review Committee and Policy Committee Reports*</td>
</tr>
<tr>
<td>a. APhA Policy Review Committee Report</td>
</tr>
<tr>
<td>b. APhA Policy Committee Report</td>
</tr>
<tr>
<td>14. APhA Policy Review Committee Report Considerations*</td>
</tr>
<tr>
<td>15. APhA Policy Committee Report Considerations*</td>
</tr>
<tr>
<td>17. Meet the Candidates for the 2018 APhA Board of Trustees Election</td>
</tr>
<tr>
<td>18. Housekeeping Announcements</td>
</tr>
<tr>
<td>19. Adjournment of the First House Session</td>
</tr>
</tbody>
</table>

*Please note: (*) asterisk indicates potential opportunities to cast votes.*
AACP (Delegates-2)  
Lynette Bradley-Baker  
Steven Scott

AAPS (Delegates-1)  
Susan Mercer

ACA (Delegates-1)  
DeAnna Leikach

ACCP (Delegates-2)  
Jill Kolesar  
C Edwin Webb

ACCP (Alt. Delegates)  
Michael Maddux  
Katherine Pham

AIHP (Delegates-2)  
Gregory Higby  
Benjamin Urick

AIHP (Alt. Delegates)  
C Wayne Weart  
William Zellmer

AIR FORCE (Delegates-2)  
Richard Caballero  
Crystal Hilaire

AIR FORCE (Alt. Delegates)  
Tracey McGaughey  
Shaoping Sumner

ALABAMA (Delegates-4)  
Darrell Craven  
Byrdena Dugan  
Ralph Sorrell  
Charles Thomas

ALABAMA (Alt. Delegates)  
Rebecca Sorrell

ALASKA (Alt. Delegates)  
Adele Davis

AMCP (Delegates-2)  
Susan Cantrell  
Marissa Schlaifer

AMCP (Alt. Delegates)  
April Shaughnessy

APhA Board (Delegates-15)  
Nancy Alvarez  
Tery Baskin  
Daniel Buffington  
Robert DiCenzo  
Linda Garrells MacLean  
Jean-Venable Goode  
Dennis Helling  
Nicki Hilliard  
Michael Hogue  
Sandra Leal  
Randal McDonough  
Thomas Menighan  
E. Michael Murphy  
Sarah Ray  
Alex Varkey

APhA-APPM (Delegates-28)  
David Barnes  
Jeffrey Bratberg  
Amber Briggs  
Andrew Bzowyckyj  
Denise Clayton  
Bin Deng  
Nico Gattas  
Stephanie Germant  
Chris Grilli  
Katelyn Johnson  
Shary Jones  
James Kirby  
Loren Kirk  
Catherine Kuhn  
Phillip Lawrence  
Ann McManis  
Bella Mehta  
Wendy Mobley-Bukstein  
Blair Sarbacker  
Michael Schuh  
Sheila Seed  
David Steeb  
Brent Thompson  
Stevie Veach  
Veronica Vornado  
Wendy Weber  
Bibi Wishart

APhA-APPM (Alt. Delegates)  
Lauren Bode  
Scott Brewster  
Andrea Brookhart  
Aimee Dietle  
Joseph Fava  
Kisha Gant  
Mark Henegar  
Nicholas Lehman  
Ryan Lindemuth  
Monali Majmudar  
Sheena Patel

Golden Peters  
Jamie Remines  
Erica Tolle

APhA-APRS (Delegates-28)  
Benjamin Aronson  
Jill Augustine  
Kevin Bain  
Edward Bednarczyk  
Deepak Bhatia  
Walter Chambliss  
Michelle Chui  
Mary Gurney  
Brandi Hamilton  
Spencer Harpe  
Adriane Irwin  
Eric Jarvi  
Laura Joglekar  
Abir Kahaleh  
Joey Mattingly  
Bill McLaughlin  
Amanda Meeker  
Karen Nagel-Edwards  
Julie Oestreich  
Anthony Olson  
Elvin Price  
Melody Ryan  
Kimberly Scarsi  
Christopher Smalley  
Gary Smith  
Ranjan Varadarajan  
Salissa Westrick  
Dennis Williams

APhA-APRS (Alt. Delegates)  
Roger Lander  
Richard Bradley Rzendzian

APhA-ASP (Delegates-28)  
Pranav Bhakta  
Christie Blaskovich  
Mary Bradley  
Allyson Cagle  
Rebecca Corvese  
Zachary Fettman  
Jason Gaines  
Daniel Galipeau  
Meryam Gharbi  
Mark Gilliam  
Alyssa Hopsicker  
Nimit Jindal  
Gillian Leung

* The numbers reflect the allotted delegates per delegation, not the actual listed delegates.  
* Individuals can only represent one delegation.
Kevin Mai
Sara Massey
Siena Meador
Shannon Parkey
Meghan Petersen
Lisa Pineros Jacobs
Priscilla Sanchez
Adrienne Simmons
Andrew Stone
Shea Terry
Natalie Tucker
Sarah Wheeler
Sierra Woods
Kelsea Zukauckas

APhA-ASP (Alt. Delegates)
Shanice Anderson
James Cong
Eric Dobberpuhl
Jimmy Godwin
Andrew Gott
Dylan Kosasaki
Katllyn Krug
Laurie Plewinski
Janhavi Punyarthi
Shannon Tuttle
Eduardo Vega Jimenez
Kelli Welter

ARIZONA (Delegates-4)
Anthony Ball
Melissa Duke
Amy Kennedy
Pamela Piotrowski

ARIZONA (Alt. Delegates)
Whitney Rice

ARKANSAS (Delegates-3)
Jeanie Monzino Smith
Brenna Neumann
Lanita White

ARKANSAS (Alt. Delegates)
Kevin Barton
Tiffany Diemer
Duane Jones
Dylan Jones

ARMY (Delegates-2)
Bryan Bailey
Jeffrey Neigh

ARMY (Alt. Delegates)
Erik De Freitas
Matthew Krull

ASCP (Delegates-2)
Brianna Palowitch
Chad Worz

ASCP (Alt. Delegates)
Arnold Clayman
Frank Grosso Rph

ASHP (Delegates-1)
Christina Martin

ASPL (Delegates-2)
Alex J Adams
Steven Gray

CALIFORNIA (Delegates-11)
Veronica Bandy
Kathleen Besinque
Richard Dang
Patty Havard
Ethan Huynh
Elizabeth Johnson
Noelle Lee
Vinson Lee
Edlen Wong
Chris Woo
George Yasutake

CALIFORNIA (Alt. Delegates)
Mike Pavlovich

COLORADO (Delegates-3)
Christine Feltman
Randi Knutsen
Morgan Payne

CONNECTICUT (Delegates-3)
Margherita Giuliano
Phil Hrncicko
Meghan Wilkosz

DELAWARE (Delegates-2)
Kevin Musto
Kimberly Robbins

DISTRICT OF COLUMBIA (Delegates-2)
Andrew Gentsles
Tamara McCants

DISTRICT OF COLUMBIA (Alt. Delegates)
Heather Free
Daneka Ivory

FLORIDA (Delegates-6)
Angela Garcia
David Mackarey
Katherine Petsos
Norman Tomaka
Scott Tomerlin
Suzanne Wise

FORMER PRESIDENTS (Delegates-34)
Lowell Anderson
Maurice Bectel
Marialice Bennett
J Bootman
Grover Bowles
Lawrence Brown
Bruce Canaday
R David Cobb
Robert Davis
George Denmark
James Doluisio

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IDAHO (Delegates-3)
Jennifer Adams
Barry Feely
Elaine Ladd

ILLINOIS (Delegates-7)
Ben Calcaterra
Starlin Haydon-Greatting
Jessica Kerr
Laura Licari
Miriam Mobley Smith
Garth Reynolds
Cynthia Russell

ILLINOIS (Alt. Delegates)
Henry Gould

INDIANA (Delegates-4)
Katherine Anderson
Broxton Davis
Gregory Fox
Meagan Williams

INDIANA (Alt. Delegates)
Leslie Lake

IOWA (Delegates-4)
Cheryl Clarke
Steve Firman
Craig Logemann
Nora Stelter

IOWA (Alt. Delegates)
Anthony Pudlo

KANSAS (Delegates-4)
Jessica Bates
Carl Benton
Robert Emerson
Emily Prohaska

KANSAS (Alt. Delegates)
Aaron Dunkel

KENTUCKY (Delegates-4)
Kimberly Crole
Patricia Freeman
Catherine Hanna
Chris Harlow

LOUISIANA (Delegates-3)
Julie Breithaupt
William Kirchain
Kenneth Wilson

LOUISIANA (Alt. Delegates)
Anthony Walker

MAINE (Delegates-2)
Daniel Mickool
Cassandra Parsons

MAINE (Alt. Delegates)
Kenneth McCall

MARYLAND (Delegates-5)
G. Hogue
Brian Hose

MARYLAND (Alt. Delegates)
DeAnna Leikach

MASSACHUSETTS (Delegates-5)
Courtney Doyle-Campbell
Trisha LaPointe
Monica Patterson

MICHIGAN (Delegates-5)
Mark Bomia
Kimberly Proffer
Larry Wagenknecht
Andrew Young

MICHIGAN (Alt. Delegates)
Dianne Malburg

MINNESOTA (Delegates-4)
Michelle Ayay
Kaitlyn Kuske
Rebecca Pickler
Anjoli Punjabi

MINNESOTA (Alt. Delegates)
Alison Knutson

MISSISSIPPI (Delegates-3)
David Allen
Lauren Bloodworth
Jillian Foster

MISSISSIPPI (Alt. Delegates)
Olivia Strain

MISSOURI (Delegates-5)
Sandra Bollinger
Maggie Bruce
Ashley Merritt
John Pieper
Anne Rogers

MISSOURI (Alt. Delegates)
Lara Kerwin

MONTANA (Delegates-2)
Paul Brand
Lyndee Fogel

NAVY (Delegates-2)
Heather Hellwig
Tiffany Scott

NAVY (Alt. Delegates)
Dean Kang
Timothy Laderach

NCPA (Delegates-2)
John Beckner

NEBRASKA (Delegates-3)
Ally Dering-Anderson
Edward DeSimone
Jennifer Tilleman

NEVADA (Delegates-3)
Mark Decerbo

NEW HAMPSHIRE (Delegates-2)
Maryann Cooper
Jessica Marx

NEW JERSEY (Delegates-5)
Elise Barry
Aakash Gandhi
Javier Rodriguez
Carmela Silvestri
Steven Zlotnick

NEW MEXICO (Delegates-3)
Jana Behrens
Michel Disco
Jennifer Ortega

NEW YORK (Delegates-6)
Christopher Daly
Karl Fiebelkorn
Ryan Lindenau
Brian Richardson
Roxanne Richardson
Martha Rumore

NORTH CAROLINA (Delegates-5)
Rebecca Chater
Cody Clifton
Evan Colmenares
Macary Marciniak
Courtney Mospan

NORTH CAROLINA (Alt. Delegates)
Christy Holland
Jennifer Wilson

NORTH DAKOTA (Delegates-1)
Sarah Schmidt

NRPhA (Delegates-2)
Erica Hanesworth
Frank North

NRPhA (Delegates-1)
Thomas Hanson

NRPhA (Alt. Delegates)
Moiria Maroney

OHIO (Delegates-8)
Dana Bachmann
Kelli Barnes
Brigid Groves
Jessica Hinson
Mitchell Howard
Ryan Schneider
Sonya Sebastian
Jeff Steckman

OHIO (Alt. Delegates)
Thad Franz
Stacey Frede

OKLAHOMA (Delegates-3)
Krista Brooks

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Eric Johnson
Katherine O'Neal
OREGON (Delegates-3)
Jill McClellan
Amy Valdez
Andrew Wash
OREGON (Alt. Delegates)
Marc Rizzo
PENNSYLVANIA (Delegates-7)
Howard Cook
Thomas Franko
Julie Gerhart-Rothholz
Daniel Hussar
Kristal Ross
Melissa Shiner
Lauren Simko
PENNSYLVANIA (Alt. Delegates)
Tanya Dougherty
PHS (Delegates-2)
William Charles
Kinbo Lee
PHS (Alt. Delegates)
Shannon Thor
RHODE ISLAND (Delegates-2)
Anita Jacobson
Daniel Lefkowitz
RHODE ISLAND (Alt. Delegates)
Lynn Pezzullo
SOUTH CAROLINA (Delegates-4)
Linda Reid
Kayce Shealy
George Vess
William Wynn
SOUTH CAROLINA (Alt. Delegates)
Elizabeth Blake
SOUTH DAKOTA (Delegates-1)
Eric Grocott
SPEAKER APPOINTED (Delegates-10)
Michael Carulli
Betsy Elswick
Marsha Gilbreath
Patrick Harper
Natasha Petry
Haniff Sealy
Larry Selkow
Anne Stella
Lucianne West
Emily Willard
TENNESSEE (Delegates-6)
McKenzie Calhoun
Jeremy Crain
Kamala Nola
Traci Poole
Leslie Shepard
Adam Welch
TENNESSEE (Alt. Delegates)
Lucy Adkins
TENNESSEE (Alt. Delegates)
Laura Beall
M. Lynn Crisman
Shara Elrod
Carole Hardin-Oliver
Mary Klein
Carol Reagan
Douglas Ried
May Woo
TENNESSEE (Alt. Delegates)
Anjanette Wyatt
VETERANS ADMIN (Delegates-2)
Anthony Morreale
Ronald Nosek
VETERANS ADMIN (Alt. Delegates)
Heather Ourth
John Santell
VIRGINIA (Delegates-6)
Olivia Kinney
William Lee
Patricia Resto
Dominic Solimando
Amy Sparkman
Adrian Wilson
VIRGINIA (Alt. Delegates)
Colleen Harmon
Krystalyn Weaver
WASHINGTON (Delegates-4)
Julie Akers
C A Leon Alzola
Collin Conway
Sara McElroy
WEST VIRGINIA (Delegates-3)
Charles Babcock
Krista Capehart
Matthew Rafa
WEST VIRGINIA (Alt. Delegates)
Shannon Gooden
WISCONSIN (Delegates-4)
Carmen Fusselman
Audrey Kostrzewa
Karen MacKinnon
Angela Marsella
WYOMING (Delegates-2)
Jaime Hornecker
Reshmi Singh
WYOMING (Alt. Delegates)
Kem Krueger

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## SEATING CHART

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

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### KEY

+ = Seat reserved for State Pharmacy Association Executive (Non-voting)  
* = Seat reserved for State Pharmacy Association Executive (Voting)  
(S) = APhA Staff Member
American Pharmacists Association House of Delegates
FIRST SESSION
Friday, March 16, 2018
3:00PM – 5:00PM

SEATING CHART BY DELEGATION NAME

<table>
<thead>
<tr>
<th>Delegation</th>
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<td>Colorado</td>
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<td>Connecticut</td>
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<td>Tables 24, 25, 26, &amp; 27</td>
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<tr>
<td>Speaker Appointed</td>
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#### SEATING CHART

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* = Seat reserved for State Pharmacy Association Executive (Voting)
(S) = APhA Staff Member
American Pharmacists Association House of Delegates
FINAL SESSION
Monday, March 19, 2018
1:30PM – 4:30PM

SEATING CHART BY DELEGATION NAME

Alabama – Table 7
Alaska – Table 6
Arizona – Table 22
Arkansas – Table 5
California – Tables 2, 3, & 4
Colorado – Table 1
Connecticut – Table 22
Delaware – Table 20
District of Columbia – Table 21
Florida – Table 21
Georgia – Table 20
Guam – Table 19
Hawaii – Table 19
Idaho – Table 19
Illinois – Table 18
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Washington – Table 46
West Virginia - 46
Wisconsin – Table 45
Wyoming – Table 45

AAPS – Table 8
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ACA – Table 23
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APhA Former Speakers – Tables 29, & 44
Speaker Appointed – Tables 39 & 40
| 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. Consideration of urgent items can be entered with a “Suspension of House Rules” at the House Session where New Business will be acted upon. |
| 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 8:00 AM 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 8:00 AM 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. Voting for the election of Speaker-elect will occur using the electronic voting system. |
Rule 1 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 2 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 3 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 4 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. Consideration of urgent items can be done 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. Re-statements 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

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 5 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 6 Nomination and Election of Speaker-elect
The House of Delegates Committee on Nominations shall consist of five delegates including the Chairman, and shall be appointed by the Immediate Past (non-incumbent) 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 7 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 8 Amendments to House of Delegates Rules
Every proposed amendment of these rules shall be submitted in writing and will require a two-third 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 9 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 10 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 not been reviewed or revised in the past 4 years and policy related to statements adopted in the previous House session.

The Speaker may engage the Policy Review Committee to review contemporary issues, where appropriate.

**Rule 11 Grammar/Punctuation Corrections**

The House shall allow the APhA Speaker and staff to the APhA House make to 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 12 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><strong>To Do This:</strong></th>
<th><strong>You Say This:</strong></th>
<th><strong>Must you interrupt speaker?</strong></th>
<th><strong>Must you be seconded?</strong></th>
<th><strong>Debatable?</strong></th>
<th><strong>Amendable?</strong></th>
<th><strong>Vote Required</strong></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>
We need your assistance in planning for the 2018-19 policy development process. Let us know what policy topics should be addressed by the 2019 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 2018-19 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.
2018 House of Delegates

Report of the House Rules Review Committee

Committee Members

Pamela Whitmire, Chair
  Janet Engle
  Kimberly Croley
  Mary Klein
  Matthew Lacroix
  Kathy Petsos
  Eric Shalita

Ex Officio Members

Michael Hogue, Speaker of the House
2017-2018
APhA House Rules Review Committee Report

The 2017-2018 APhA House Rules Review Committee (HRRC) consists of the following APhA members and long-time Delegates:

Pamela Whitmire, Chair
Anderson, SC

Janet Engle
Chicago, IL

Matthew Lacroix
Gorham, ME

Kimberly Croley
Corbin, KY

Kathy Petsos
Cape Canaveral, FL

Mary Klein
Abilene, TX

Eric Shalita
Las Vegas, NV

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.

2017-2018 Specific Charges / Work Plan
This year, the following charges were assigned to the HRRC:

The HRRC met via conference call on May 3, 2017 and May 22, 2017 and made the following recommendations.

1. Observation of the 2017 APhA House of Delegates
Upon completing its review of the proceedings of the 2017 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 2017 APhA House of Delegates. The Committee observed, reviewed, and discussed challenges and opportunities to maximize the efficiency of House operations. One change to the APhA House of Delegates Rules was suggested for consideration by Delegates (see Sections 3 and 5).

The HRRC reviewed, from a grammatical and copy-editing perspective, the policy language approved by the 2017 House of Delegates. Upon completing its review, the HRRC took the following action:

> By CONSENT, the House Rules Review Committee approved the 2017 Report of the APhA House of Delegates Report 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 report of unfilled delegate seats prepared by APhA staff. In accordance with APhA Bylaws, staff began tracking the number of unfilled seats in 2014 and staff began enacting procedures for inactivating delegate seats leading up to the 2017 House session.
  - The HRRC discussed the continued need for active delegates, but felt no changes should be made to the Bylaws related to the inactivation of delegate seats due to inactivity.
  - The HRRC reviewed existing procedures for communications out to Delegations regarding an inactivated delegate seat. The HRRC also reviewed the process for reactivating a delegate seat and discussed there should be consequence for not filling a reactivated delegate seat during the next meeting and all inactive seats should be eligible for reactivation at any time during the year.
  - The HRRC also discussed the possibility of a mandatory minimum amount of delegate seats and recommends that no minimum exist at this time as long as all seats are able to reactivated if requested through the proper process.

- **Urgent New Business Items**
  - The HRRC reviewed and discussed House Rule 4 (New Business) specifically related to how urgent new business items are addressed by the House. Based on the discussion, the HRRC recommends a change to House Rule 4 (see Section 5)
  - The HRRC recommends a modification to how urgent new business items are introduced to the House to allow for a review by the New Business Review Committee concurrent with the regular new business item process.
  - The HRRC also recommends that new business items be addressed in a specific order so that it is clear to delegates where the new business item originated from, be it the Policy Review Committee, the regular new business item process, or the urgent new business item process.
• Policy Review Process  
o The HRRC reviewed the Policy Review Committee’s (PRC) procedures and recommended no changes to House rule 10 (Policy Review Committee). The HRRC did discuss how it is confusing when the PRC submits a new business item that restates existing policy.
  o The HRRC recommends the Policy Review Committee continue to explain why an item was submitted as a New Business Item in the PRC report. Additionally, the PRC needs to be clear in a New Business Item submission how the item is related to existing policy to prevent confusion.

• Electronic Voting  
o 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 according with Robert’s Rules of Order and there should not be a mandate to always use electronic keypad voting.
  o The HRRC discussed the concept of using phones to cast votes instead of electronic keypads and does not recommend this practice at this time.

• Delegate Education  
o 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 2017 House session.

• House of Delegate Materials  
o 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.

• Board of Trustee Speeches  
o The HRRC recommends the continuation of speeches from Board of Trustee candidates.
  o 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.

• Introduction of a Consent Agenda  
o The HRRC discussed opportunities to streamline House sessions and recommends the implementation of a Consent Agenda beginning at the 2019 House sessions.
  o In consultation with the APhA Parliamentarian, the HRRC recommends the 2018-2019 HRRC approve the House Schedule of Events to include a Consent Agenda for the first session that addresses the following with a single vote: credential report, adoption of agenda and rules, and approval of the HRRC report.
  o In consultation with the APhA Parliamentarian, the HRRC recommends the 2018-2019 HRRC approve the House Schedule of Events to include a Consent Agenda for the second session that addresses the following with a single vote: credentials report and the agenda and rules.

• Virtual House  
o The HRRC discussed the potential for virtual House activities and recommends APhA conduct research into what options may work for APhA to conduct a virtual house session. The HRRC also recommends that any potential needed rule changes to conduct a virtual house be identified.
4. Review of 2018 APhA House of Delegates Activities Schedule

The HRRC reviewed and evaluated the 2018 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 schedule and Delegate materials for the 2018 APhA House of Delegates.

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 4 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. Consideration of urgent items can be done with a suspension of House rules at the House Session where New Business will be acted upon.

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 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. Re-statements 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

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.

By CONSENT, the House Rules Review Committee approves the APhA House of Delegates Rules of Procedure as proposed and recommends these revisions to be effective immediately upon adoption by the House of Delegates.

This report is presented for approval by the APhA House of Delegates by Pamela Whitmire, Chair of the House Rules Review Committee.
2018 House of Delegates
Report of the Policy Review Committee

Policies last reviewed in 2013
Policies Related to Newly Adopted Policies from 2017 HOD

❖ Statements Organized by Recommendation

Committee Members

Andrew Bzowyckyj, Chair
Michael Carulli
Betsy Elswick
Patrick Harper
Laura Joglekar
Kimberly Proffer
Carol Reagan
L. Douglas Ried
Kristal Ross
Lucy West

Ex Officio

Michael Hogue, Speaker of the House
POLICY STATEMENTS

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

2002, 1984 Depiction of Pharmacists in Public
APhA supports the development of guidelines or standards to enhance the depiction of the pharmacy profession in all public media.

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

2003, 2000 Emergency Contraception
APhA supports the voluntary involvement of pharmacists, in collaboration with other health care providers, in emergency contraceptive programs that include patient evaluation, patient education, and direct provision of emergency contraceptive medications.

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

2013 Revisions to the Medication Classification System
1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug classification paradigms for prescription and nonprescription medications to allow greater access to certain medications under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.
2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug classification system.
3. APhA supports a patient care delivery model built on coordination and communication between pharmacists and other health care team members in the evaluation and management of care delivery.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications under FDA’s approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications under FDA’s defined conditions of safe use.
6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications under FDA’s approved conditions of safe use.
7. APhA encourages the inclusion of medications and services provided under FDA’s defined conditions of safe use within health benefit coverage.
8. APhA supports compensation of pharmacists and other health care professionals for the provision of services related to FDA’s defined conditions of safe use programs.

Comments: The Policy Review Committee recommends RETAINING these policy statements, but intends to submit a New Business Item to modify language in statements 1, 2, 4, 5, 6, and 7 to incorporate medical devices into these statements. The New Business Item would RETAIN policy statements #3 and #8 as originally written.
4. The Committee recommends RETAINING the following policy statement as written.

**2006 Drug Classification System**

1. APhA supports restructuring the current drug classification system and drug approval process. Evidence should drive the restructuring beyond the current prescription and nonprescription classes to ensure appropriate access to medications and pharmacist services and improve medication use and outcomes.
2. APhA encourages pharmacists to exercise their professional judgment to manage access to nonprescription medications and dietary supplements to facilitate patient/caregiver interaction with their pharmacist.

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

**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.

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

**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.

7. The Committee recommends RETAINING 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 RETAINING this policy statement, but recommends referral of this policy statement along with 2012, 2004, 1992 Drug Product Packaging and 2006, 2003 Unit-of-Use Packaging as a group of statements, at the discretion of the Speaker of the House, to a special House committee for further and specialized review.
8. 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.

**Comments:** The Policy Review Committee recommends RETAINING this policy statement, but recommends referral of this policy statement along with 2012 Counterfeit Medication and Unit-of-use Packaging and 2006, 2003 Unit-of-Use Packaging as a group of statements, at the discretion of the Speaker of the House, to a special House committee for further and specialized review.

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

**2006, 2003 Unit-of-Use Packaging**

1. APhA encourages the continued development, distribution, and use of unit-of-use packaging as the industry standard to enhance patient safety, patient compliance, and efficiencies in drug distribution.
2. APhA shall collaborate with the pharmaceutical industry, third-party payers, and appropriate federal agencies to effect the changes necessary for the adoption of unit-of-use packaging as the industry standard.
3. APhA encourages the enactment of legislation and regulations to permit pharmacists to modify prescribed quantities to correspond with commercially available unit-of-use packages.

**Comments:** The Policy Review Committee recommends RETAINING this policy statement, but recommends referral of this policy statement along with 2012 Counterfeit Medication and Unit-of-use Packaging and 2012, 2004, 1992 Drug Product Packaging as a group of statements, at the discretion of the Speaker of the House, to a special House committee for further and specialized review.

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

**2012 Medication Verification**

APhA encourages including a description of a medication’s appearance on the pharmacy label or receipt as a means of reducing medication errors and distribution of counterfeit medications.
11. The Committee recommends RETAINING the following policy statement as written.

2008 Experiential Education

2. APhA encourages the American Association of Colleges of Pharmacy (AACP), in collaboration with state boards of pharmacy, practitioner organizations, and other stakeholders, to develop national standardization among schools and colleges of pharmacy to improve the quality of student pharmacists’ experiential education. This standardization should be adopted by all schools and colleges of pharmacy and should include the following:
   (a) a preceptor training program;
   (b) a model instrument for preceptors to evaluate student pharmacist performance in required pharmacy practice experiences;
   (c) a set of quality indicators for each required pharmacy practice experience; and
   (d) a report of quality indicator outcomes made available to all schools and colleges of pharmacy, faculty, and current and prospective students.

3. APhA urges schools and colleges of pharmacy to dedicate adequate and equitable financial and human resources to experiential education.

Comments: This item is included in both the RETAINING and ARCHIVING sections of this report. The Policy Review Committee recommends RETAINING statements #2 and #3 as these items are still relevant. The Policy Review Committee recommends ARCHIVING statement #1 as the committee believes this has been accomplished through the ACPE standards. Item #1 is shown in the ARCHIVED section of this report. Additionally, the Policy Review Committee recommends that the topic of Experiential Education be submitted into the Policy Development Process for further review by future Policy Committees.

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

2013, 2008 Pharmacy Practice-based Research Networks

1. APhA supports establishment of pharmacy practice-based research networks (PBRNs) to strengthen the evidence base in support of pharmacists’ patient care services.

2. APhA encourages collaborations among stakeholders to determine the minimal infrastructure and resources needed to develop and implement local, regional, and nationwide networks for performing pharmacy practice-based research.

3. APhA encourages pharmacy residency programs to actively participate in pharmacy PBRNs (practice-based research networks).

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

2005, 1990 Pharmacy Schools’ Curriculum and Contemporary Pharmacy Needs

1. APhA will work with schools and colleges of pharmacy and pharmacy organizations to address differences between contemporary pharmacy practice and curriculum offerings.

2. APhA encourages pharmacists to cooperate with schools and colleges of pharmacy by participating as preceptors and permitting their practices to be used as experiential sites.

Comments: The Policy Review committee recommends RETAINING both policy statements, but intends to also submit a New Business Item to clarify and modernize content in statement #1. The New Business Item, if adopted by the House, would replace statement #1 with updated language.
14. The Committee recommends RETAINING the following policy statement as written.

2005 Regulation of Student Pharmacists’ Practice Experience
1. APhA encourages state boards of pharmacy to use the title “student pharmacist” to identify all students enrolled in their professional years of pharmacy education in an Accreditation Council for Pharmacy Education (ACPE) accredited program.
2. APhA encourages state boards of pharmacy to permit a student pharmacist to perform the duties of a pharmacist within the applicable state’s scope of practice under a pharmacist’s supervision. Preceptors shall consider the experience and education of student pharmacists when providing pharmacy practice opportunities.

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

2013, 2008 Residency Training for Pharmacists
1. APhA urges continued growth in the number of accredited pharmacy residency positions in all practice settings to better meet the future health care needs of the nation.
2. APhA encourages active involvement of schools and colleges of pharmacy in the development and advancement of accredited pharmacy practice residency programs.
3. APhA advocates for the allocation of adequate funding for accredited pharmacy residencies in all practice settings by governmental and other entities.
4. APhA supports postgraduate training for new PharmD graduates.
5. APhA supports accreditation of all pharmacy residency programs by federally recognized accrediting bodies to ensure quality training experiences.

16. 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.

Comments: The Policy Review committee recommends RETAINING these policy statements, but recommends referral, at the discretion of the Speaker of the House, to a special House committee for further and specialized review.

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

2013, 2009 Independent Practice of Pharmacists

1. APhA recommends that health plans and payers contract with and appropriately compensate individual pharmacist providers for the level of care rendered without requiring the pharmacist to be associated with a pharmacy.
2. APhA supports adoption of state laws and rules pertaining to the independent practice of pharmacists when those laws and rules are consistent with APhA policy.
3. APhA, recognizing the positive impact that pharmacists can have in meeting unmet needs and managing medical conditions, supports the adoption of laws and regulations and the creation of
payment mechanisms for appropriately trained pharmacists to autonomously provide patient care services, including prescribing, as part of the health care team.

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

2008 Internet Access by Pharmacists
   APhA supports ready access to Internet resources by pharmacists at their practice sites to facilitate delivery of patient care and to support professional development.

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

2013 Medication Take-Back/Disposal Programs
   1. APhA encourages pharmacist involvement in the planning and coordination of medication take-back programs for the purpose of disposal.
   2. APhA supports increasing public awareness regarding medication take-back programs for the purpose of disposal.
   3. APhA urges public and private stakeholders, including local, state, and federal agencies, to coordinate and create uniform, standardized regulations, including issues related to liability and sustainable funding sources, for the proper and safe disposal of unused medications.
   4. APhA recommends ongoing medication take-back and disposal programs.

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

1990 Proper Handling & Disposal of Hazardous Pharmaceuticals & Associated Supplies & Materials
   1. APhA supports the proper handling and disposal of hazardous, pharmaceutical products and associated supplies and materials by health professionals and by patients to whom such products, supplies, and materials are provided.
   2. APhA supports involvement with representatives from other health professional organizations, industry, and government to develop recommendations for the proper handling and disposal of hazardous pharmaceuticals and associated supplies and materials.
   3. APhA supports the development of educational programs for health professionals and patients on the proper handling and disposal of hazardous pharmaceuticals and associated supplies and materials.
21. The Committee recommends RETAINING the following policy statement as written.

**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.

22. 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.

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

**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.

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

**1987 Compensation for Cognitive Services**
1. APhA recognizes that pharmacists provide to patients cognitive services (i.e., services requiring professional judgment) that may or may not be related to the dispensing or sale of a product.
2. APhA supports compensation of pharmacists for providing cognitive services (i.e., services requiring professional judgment) that may or may not be related to the dispensing or sale of a product.
25. The Committee recommends RETAINING the following policy statement as written.

**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.

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

**1985 Registration of Facilities Involved in the Storage and Issuing of Legend Drugs to Patients**

APhA supports enactment of state and federal laws and regulations that would require registration with the state boards of pharmacy of all facilities involved in the storage and issuing of legend drugs to patients, provided that such registration does not restrict the pharmacist from providing professional services independent of a facility.

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

**2008, 2001 Regulatory Compliance/Regulatory Burden**

APhA supports measures that protect the patient, public, and employees from pharmacy conditions that pose a threat to health.

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

**2004, 1978 State Boards of Pharmacy/Inspections**

1. APhA supports inspections of pharmacies and peer review of pharmacists that promote high-quality pharmaceutical service and thereby serve to improve public health.
2. APhA opposes the use of criminal investigative techniques during routine noncriminal pharmacy inspections.
3. APhA supports regulation and inspection by boards of pharmacy of all facilities within a state at which drugs are dispensed, stored, or offered for sale in the same manner as pharmacies.
29. The Committee recommends RETAINING the following policy statement as written.

2004, 1996 Technician Licensure and Registration
   1. APhA recognizes the following definitions with regards to technician licensure and registration:
      (a) Licensure: The process by which an agency of government grants permission an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Within pharmacy, a pharmacist is licensed by a State Board of Pharmacy.
      (b) Registration: The process of making a list or being enrolled in an existing list.

30. 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.

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

2013, 2008 Re-use of devices intended for “Single-Use”
   APhA opposes the reuse of devices intended for “single use” in the screening and management of patients consistent with the Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) guidelines.

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

2009 Disparities in Healthcare
   APhA supports elimination of disparities in the health care delivery.
33. The Committee recommends RETAINING the following policy statement as written.

2012, 1991 Recruitment of a Diverse Population into Pharmacy
1. APhA supports a vigorous long term program for the recruitment of a diverse population of student pharmacists into the pharmacy profession.
2. APhA encourages the development and regular updating of comprehensive recruitment materials, directed toward diversity and inclusion, that address such issues as pharmacy career opportunities, financial aid, and educational prerequisites, and that highlight professional diverse role models.
3. APhA encourages national, state, and local associations; schools; students; and industry to create a network of pharmacists who would serve as role models for a diverse population of student pharmacists.
4. APhA supports the development of guidelines that assist schools of pharmacy in implementing diversity and inclusion initiatives into student pharmacist recruitment programs.

34. 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.

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

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.

Comments: The Policy Review Committee recommends RETAINING this policy statement, but recommends referral, at the discretion of the Speaker of the House, to a special House committee for further and specialized review.
36. The Committee recommends **RETAINING** the following policy statement as written.

**2013, 1995  Pharmacists’ Role in the Development and Implementation of Evidence-Based Clinical Guidelines**

1. APhA advocates direct involvement of pharmacists in the development, evaluation, and implementation of evidence-based clinical guidelines. Well-designed guidelines promote an interdisciplinary team approach to patient care that utilizes pharmacists' expertise in optimizing patient outcomes.
2. APhA believes that evidence-based clinical guidelines should promote optimal patient care built on the best available scientific data. These guidelines should be developed using an interdisciplinary approach and should be evaluated regularly to ensure that they reflect current practice standards.
3. APhA should promote educational programs, products, and services that facilitate the participation of pharmacists in the development, evaluation, and implementation of evidence-based practice guidelines in all practice settings.
4. APhA advocates the use by pharmacists, in all practice settings, of evidence-based practice guidelines for pharmaceutical care built on the best scientific data to optimize patient outcomes. These guidelines should be developed using an interdisciplinary approach and should be evaluated regularly to ensure that they reflect current practice standards.

37. 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.

38. The Committee recommends **RETAINING** the following policy statement as written.

**2013, 1980  Medication Selection by Pharmacists**

APhA supports the concept of a team approach to health care in which health care professionals perform those functions for which they are educated. APhA recognizes that the pharmacist is the expert on drugs and drug therapy on the health care team and supports a medication selection role for the pharmacist, based on the specific diagnosis of a qualified health care practitioner.

39. The Committee recommends **RETAINING** the following policy statement as written.

**2012, 2002, 1964  Health Education: Selection of Pharmacist**

APhA supports education of consumers about the importance of selecting their personal pharmacist to assist them in the proper use of all medications and medical devices.
40. The Committee recommends RETAINING the following policy statement as written.

**2010, 2001 Prescription Order Requirements**

1. APhA supports the use of technology to facilitate the transmission of prescription order information from the prescriber to the pharmacist of the patient’s choice at no additional cost to the pharmacy.
2. APhA supports the use of technology where appropriate standards for patient confidentiality and prescriber and pharmacist verification are established.
3. APhA supports the transmission of complete prescriber information on or with the prescription order that enables the pharmacist to readily identify and facilitate communication with the prescriber.
4. APhA supports the use of specific instructions with prescription orders. Use of potentially confusing terminology (such as “as directed”, unclear use of Latin phrases, confusing abbreviations, etc.) should be avoided.
5. APhA supports the inclusion of the diagnosis or indication for use for which the medication is ordered on or with the transmission of the prescription order by use of standard diagnosis codes or within the directions for use. APhA further supports the inclusion of patient-specific information on or with the prescription order where appropriate.
6. APhA supports public education about the benefits and risks of technological advances in pharmacy practice.

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

**2005, 1971 Cigarette Sales in Pharmacies**

1. APhA recommends that tobacco products not be sold in pharmacies.
2. APhA recommends that state and local pharmacist associations develop similar policy statements for their membership and increase their involvement in public educational programs regarding the health hazards of smoking.
3. APhA recommends that individual pharmacists give particular attention to educating young people on the health hazards of smoking.
4. APhA recommends that APhA-ASP develop projects aimed at educating young people on the health hazards of smoking, such as visiting schools and conducting health education programs.

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

**1999 Promotion of Pharmaceutical Care**

1. APhA should continue to promote to the public the concepts and benefits of pharmaceutical care, differentiating pharmaceutical care practice from other pharmacy services.
2. APhA opposes the use of the term "pharmaceutical care" by any individual or entity unless the pharmaceutical care service provided by the individual or entity incorporates the concepts specified in the APhA Principles of Practice for Pharmaceutical Care.
43. The Committee recommends RETAINING the following policy statement as written.

2013, 2001, 1994 Pharmacist-Patient-Prescriber-Payer Responsibilities in Appropriate Drug Use

1. APhA advocates the following guidelines for pharmacist-patient-prescriber-payer responsibilities in appropriate drug use:

(a) Pharmacists’ Responsibilities
• Serve as a drug information resource;
• Provide primary care;
• Collaborate with the prescriber and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
• Identify formulary or generic products as a means to reduce costs;
• Intervene on behalf of the patient to identify alternate therapies;
• Educate the patient about the treatment regimen and expectations, and verify the patient’s understanding;
• Identify, prevent, resolve, and report drug-related problems;
• Document and communicate pharmaceutical care activities;
• Monitor drug therapy in collaboration with the patient and prescriber to ensure compliance and assess therapeutic outcomes;
• Maintain an accurate and efficient drug distribution system; and
• Maintain proficiency through continuing education.

(b) Patients’ Responsibilities
• Assume a responsibility for wellness;
• Understand the coverage policies of their benefit plan;
• Share complete information with providers, including demographics and payment mechanism(s);
• Share complete information regarding medical history, lifestyle, diet, use of prescription and over-the-counter medications, and other substances;
• Participate in the design of the treatment regimen;
• Understand the treatment regimen and expected outcomes;
• Adhere to the treatment regimen; and
• Alert prescribers and pharmacists to possible drug-related problems or changes in health status.

(c) Prescribers’ Responsibilities
• Assess and diagnose the patient;
• Share pertinent information in collaboration with the pharmacist and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
• Clearly communicate the treatment plan and its intended outcomes to the patient directly or in collaboration with the pharmacist;
• Remain alert to the possible occurrence of drug-related problems and initiate needed changes in therapy;
• Collaborate with the patient and the pharmacist in drug therapy monitoring; and
• Maintain proficiency through continuing medical education.

(d) Payers’ Responsibilities
• Determine the objectives and desired benefits of pharmacy service;
• Design the coverage with patient and provider input using products and services to produce beneficial outcomes;
• Contract with providers on the basis of outcomes and efficient use of resources;
• Adopt efficient, clear, and uniform administrative processes;
• Communicate requirements of compensation for levels of care;
• Educate patients and providers about current eligibility and benefit information;
• Expeditiously process payments; and
• Be responsive to advances in contemporary practice.

Comments: The Policy Review Committee recommends RETAINING this policy, but additionally recommends referral, at the discretion of the Speaker of the House, to a special House committee for further and focused review. One potential amendment discussed by the Policy Review Committee was adding “with provider input” within section (d) Payers’ Responsibilities. As currently written, a pharmacists input may not be included when considering desired benefits of pharmacy service.

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

2012, 2005, 1969 Medicare and Patient Care Service

1. APhA believes that Health care, including the essential component of patient care services, should be made available to as many people as possible in our society through the most economical system compatible with an acceptable standard of quality.
2. APhA should support the Part B mechanism which is the voluntary supplementary medical insurance program financed equally by beneficiaries and the government.
3. APhA should oppose legislation which would restrict the Medicare drug benefit to specific, chronic diseases.
4. APhA should support the inclusion of patient care services under Medicare or any other federal financing mechanism, providing the program is designed to help persons who need it most and is administratively efficient and economical.

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

2005, 1993 Payment System Reform

1. APhA must advocate reform of pharmacy payment systems to enhance the delivery of comprehensive medication-use management services.
2. APhA must assume a leadership role, in cooperation with other pharmacy organizations, patients, other providers of health services, and third-party payers, in developing a payment system reform plan.
3. APhA should encourage universal acceptance of all components of pharmaceutical care and their integration into pharmacy practice to support payment for services.
46. The Committee recommends RETAINING the following policy statement as written.

1994  Product and Payment Systems
   1. APhA shall work with public and private sectors in developing timely educational processes which assist pharmacists to implement patient care, understand new payment systems, and apply emerging therapeutic advances to achieve desired patient outcomes.
   2. APhA supports payment systems that distinguish between compensation for the provision of pharmaceutical care and reimbursement for product distribution.
   3. APhA shall participate in the identification, development, and implementation of models for procurement and handling of therapeutic and diagnostic pharmaceutical products and devices which assure the continuous provision of pharmaceutical care by pharmacists.

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

1979  Consideration of the Equal Rights Amendment
   APhA supports efforts to assure equal rights of all persons.
AMENDED POLICY STATEMENTS

48. The Committee recommends AMENDING the following policy statement as written.

2009 Medication Disposal
1. APhA encourages appropriate public and private partnerships to accept responsibility for the costs of implementing safe medication disposal programs for consumers. Furthermore, APhA urges DEA to permit the safe disposal of controlled substances by consumers or on their behalf.
2. APhA encourages provision of patient-appropriate quantities of medication supplies to minimize unused medications and unnecessary medication disposal.

Comments: The Policy Review Committee recommends AMENDING this policy to include “or on their behalf” to reflect the instance where police or pharmacy staff dispose of medications on behalf of a patient. The Committee discussed the potential for this to change the original intent of the policy statement, but felt this amendment was within the scope of work for the Committee as this amendment reflects what is currently happening in practice today.
ARCHIVED POLICY STATEMENTS

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

2005, 1990 Expansion and Recognition of Internship, Externship, and Clerkships

1. APhA encourages schools and colleges of pharmacy to establish and maintain experiential education programs in nontraditional areas of practice.
2. APhA encourages state boards of pharmacy to accept, at least on an hour-for-hour basis, hours of experiential education obtained in nontraditional areas of pharmacy practice as fulfilling internship hour requirements.

Comments: The Policy Review Committee recommends ARCHIVING this policy as items mentioned in the policy statements are common place in pharmacy education and this is not needed on the active APhA policy books.

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

2008 Experiential Education

1. APhA urges state boards of pharmacy, the Accreditation Council for Pharmacy Education (ACPE), the American Association of Colleges of Pharmacy (AACP), and other professional associations; employers; and other stakeholders to collaborate in the development of a blueprint that evaluates, streamlines, and consolidates all student pharmacists’ experiential education requirements.

Comments: This item is included in both the RETAINING and ARCHIVING sections of this report. The Policy Review Committee recommends RETAINING statements #2 and #3 as these items are still relevant. The Policy Review Committee recommends ARCHIVING statements #1 as the committee believes this has been accomplished through the ACPE standards. Item #1 is shown in the ARCHIVED section of this report. Additionally, the Policy Review Committee recommends that the topic of Experiential Education be submitted into the Policy Development Process for further review by future Policy Committees.
51. The Committee recommends ARCHIVING the following policy statement as written.

**2008 Pharmacy Technician Education and Training**

1. APhA reaffirms the 2005/2001/1996 Control of Distribution System policy, which states that APhA supports pharmacists’ authority to control the distribution process and personnel involved and the responsibility for all completed medication orders, regardless of practice setting.
2. APhA supports nationally recognized standards and guidelines for the accreditation of pharmacy technician education and training programs.
3. APhA supports the continued growth of accredited education and training programs that develop qualified pharmacy technicians who will support pharmacists in ensuring patient safety and enhancing patient care.
4. APhA supports the following minimum requirements for all new pharmacy technicians by the year 2015:
   (a) successful completion of an accredited education and training program and
   (b) certification by the Pharmacy Technician Certification Board (PTCB).
5. APhA supports state board of pharmacy regulations that require pharmacy technicians to meet minimum standards of education, training, and certification. APhA also encourages state boards of pharmacy to develop a phase-in process for current pharmacy technicians.

**Comments:** The Policy Review Committee recommends ARCHIVING this policy statement as the newly adopted 2017 Pharmacy Technician Education, Training, and Development policy language encompasses the intent of this policy.

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

**2012, 1987 Pharmacists’ Authority to Select Medications**

APhA supports authority for pharmacists to select nonprescription and prescription medications as part of pharmacists’ responsibilities to design, implement, and monitor drug regimens for patients, in consultation with practitioners when appropriate.

**Comments:** The Policy Review Committee recommends ARCHIVING this policy as more contemporary and comprehensive statements exists in the 2017 Patient Access to Pharmacist-Prescribed Medications policy language.
2018 House of Delegates
Report of the Policy Committee

- Pharmacist Workplace Environment and Patient Safety
- Use of Pharmacogenomic Data within Pharmacy Practice
- Proactive Immunization Assessment and Immunization Information Systems

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Gregory Fox
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Christopher Grilli
Natasha Petry
Garth K. Reynolds
Annie Stella
Adam C. Welch

Ex Officio
Michael D. Hogue, 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.
The committee recommends that the Association adopt the following statements:

1. APhA supports staffing models that promote safe provision of patient care services and access to medications.
   [Refer to Summary of Discussion Items 3, 4, 5.]

2. APhA opposes the setting of quotas or use of time-oriented metrics that may jeopardize patient care and safety.
   [Refer to Summary of Discussion Items 6, 7, 8, 9.]

3. APhA denounces reimbursement systems, including the practices of PBM and other payers that contribute to a workplace environment that negatively has an impact on 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.
   [Refer to Summary of Discussion Items 10, 11, 12, 13.]

4. APhA urges pharmacy practice employers to establish collaborative mechanisms that engage the pharmacist in charge of each practice, pharmacists, and pharmacy staff in addressing workplace issues that may have an impact on patient safety.
   [Refer to Summary of Discussion Items 8, 9, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23.]

5. APhA urges employers to regularly and systematically examine and resolve workplace issues that may negatively have an impact on patient safety.
   [Refer to Summary of Discussion Items 8, 9, 19, 20, 21, 22, 24.]

6. APhA opposes retaliation against pharmacy staff for reporting workplace issues that may negatively have an impact on patient safety.
   [Refer to Summary of Discussion Items 9, 19, 23, 25, 26, 27.]
Summary of Discussion

1. The committee recognizes that workplace issues is one of high importance in our profession. The breadth and depth of the issues in this space are daunting when considered in total. The committee’s charge from the APhA Board of Trustees was to focus on those aspects of workplace issues which directly impact patient safety. As a result, the proposed policies necessarily do not address every possible workplace issue. The committee also recognizes that there are site-specific factors which must be taken into account when addressing the workplace as a place for safe and effective patient care, inclusive of dispensing. The committee is hopeful that these contemporary proposed policy statements adopted by the House taken together with previously adopted policy will serve as a catalyst for collaboration between pharmacists and their employers to improve workplace issues and ensure patient safety.

2. The committee’s intent in addressing this issue is that it applies to all practice settings.

3. The committee reviewed existing APhA 2001 Work Schedules policy and felt staffing models should be re-emphasized within this policy topic as it relates to patient safety.

4. The committee discussed the practice specific needs in regards to the use of pharmacy technicians and technician ratios. They felt practice settings need to address their specific needs that minimize safety risks, and therefore decided not to make a specific statement regarding pharmacist to technician ratios. The committee also recognized staffing ratios could restrict patient access to pharmacy services.

5. The committee discussed the use of the term “medications” and agreed it best reflects pharmacy practice as opposed to “drug products”.

6. The committee specifically included the term “jeopardize” in the second statement to emphasize the focus on opposing harm to patients.

7. The Committee considered adding details qualifying quotas such as, “per shift” or “per week”, but did not include this terminology to keep the policy statement focused on the opposition of quotas. Additionally, the Committee considered adding examples of quotas such as numbers of prescriptions filled, immunizations administered, and other services provided by a pharmacist, but determined the statement should be left broad. The Committee wished to emphasis APhA’s Impact on the Pharmacist’ Working Conditions on Public Safety policy statement related to quotas that has been in existence since 1995.
8. The committee agreed that employers should empower their pharmacists to use their professional judgement to perform their job in a safe and effective manner for their patients.

9. The committee agreed that including the term “may” is more inclusive because it incorporates the possibility of harm (e.g. near miss reports).

10. The committee specifically used the term “reimbursement” as opposed to “compensation” or other similar terminology since “reimbursement” is most commonly used by the Centers for Medicare & Medicaid Services (CMS).

11. The committee considered including the term “sustainable” in front of “payment policies” in the second half of statement three. The committee excluded the term “sustainable” so as not to change the focus of the statement toward sustainable operations of a pharmacy from the promotion of safe patient care delivery.

12. The Committee recognizes that the focus of statement three is an urgent issue and is perhaps having the greatest negative impact on pharmacists’ ability to provide safe care.

13. The committee intentionally included two statements within this single policy. The purpose is to identify the systems that APhA denounces and who (i.e. public and private policy makers) should specifically establish policies on this issue.

14. By including “pharmacists and pharmacy staff” in statement four, the committee intends for front-line or practice-level staff involvement of pharmacists and pharmacy staff in assuring patient safety. The issue needs to be addressed by the broad spectrum of individuals engaged in the pharmacy practice (e.g. management, care providers, support staff, etc.)

15. The committee agreed the term “sites” is most appropriate to include any pharmacy practice regardless of specific setting. The committee acknowledge that statement four is meant to develop mechanisms that are meaningful to the practice site and provide accountability.

16. The committee acknowledged that inclusion of “pharmacist in charge”, “pharmacist”, and “pharmacy staff” are the appropriate individuals to develop practice site mechanisms. The pharmacist-in-charge may or may not be engaged in the provision of pharmacy services and therefore the committee intended for the pharmacist providing dispensing or patient care services be included in this activity. The committee acknowledged that these individuals practice on the front-line and need to be specifically involved in the process. The committee felt strongly that the accountability, responsibility and authority for practice-level activities of the pharmacist-in-charge related to patient safety, needs to be reinforced.
17. The committee discussed the importance of including the term “collaborative” when referring to mechanisms, because shared accountability is needed between the individuals and the organization for creating safe systems in the work environment.

18. The committee discussed the AHRQ definition of a “just culture” methodology. More information can be found at https://psnet.ahrq.gov/primers/primer/5/safety-culture.

19. The committee reviewed APhA 2012, 2007, 1970 Employment Standards Policy Statement dating back to 1970. Specifically statement 6 in the first section states, “employed pharmacists are obligated to unhesitantly bring to the attention of their employers all matters which will assist the employers in maintaining professional standards and successful practices.”

20. The committee discussed current state level issues where State Boards of Pharmacy are unable to investigate anonymously reported workplace issues, which effect patient safety.

21. The committee considered combining statements four and five, but felt each of these statements needed to stand alone to focus on accountability of the employer and involvement of front-line pharmacy practice staff.

22. The committee discussed the concept of continuous quality improvement (CQI) procedures to review this process and how CQI will be an important component, among other means, to facilitate this review process.

23. The committee reviewed APhA 2009 Pharmacist’s Role in Patient Safety and determined that statement 5 of this existing policy refers specifically to the systems for reporting and misses a focus on protecting pharmacists and pharmacy staff who report workplace issues from retaliation.

24. The committee discussed how the term “employers” was all inclusive to different pharmacy practice settings and would be the most appropriate for this statement.

25. During the committee’s discussion on the scope of retaliation, it was envisioned to protect against termination, work schedule modification, unsubstantiated performance evaluations.

26. The committee discussed the importance for pharmacy staff to report workplace issues and agreed that anyone who is implicated through a proper investigation should still have any necessary consequences be imposed if there are identified employee conduct and service issues, but just the reporting of workplace issues should not lead to retaliation by an employer. The intent of this statement is to not penalize pharmacy personnel just because they reported a potential workplace issue that could negatively impact patient safety.
27. The committee reviewed and referred to the **Occupational Safety and Health Act (OSH Act), Section 11(c)** as this is the general statutory provision that provides general protection from retaliation. Additionally, the committee noted that a whistleblower protection program exists external from the existing OSH Act regulations. In general, OSHA, Equal Employment Opportunity Center (EEOC), and other whistleblower statutes and programs protect employees from retaliation and an employer cannot retaliate by taking "adverse action" against workers who report injuries, safety concerns, or other protected activity.

28. The committee reviewed existing APhA policy **2004 Automation and Technology in Pharmacy Practice** and felt statement two of this existing policy addresses the use of technology and automation to ensure safety. While drafting this report of proposed statements, the committee felt the proposed statements encompassed a call for review of current systems and system alerts (e.g. drug interaction alerts) to resolve issues that may contribute to patient safety concerns.

29. The Committee encourages pharmacists and pharmacies to utilize patient safety practice assessments and resources from the Institute for Safe Medicine Practices (ISMP) and other patient safety organizations.

30. The committee discussed the potential for a pharmacy accreditation process that evaluates the work environment, staffing, employment policies and procedures and other workplace factors which impact the safe provision of medication and patient care by pharmacists. The committee agreed that APhA **2011 Pharmacy Practice Accreditation** policy statements encompass APhA’s current stance on pharmacy practice accreditation, which opposes a mandatory pharmacy accreditation.
Pharmacist Workplace Environment and Patient Safety

Background Paper Prepared for the 2017–2018 APhA Policy Committee
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Project Manager
Purdue University, College of Pharmacy

Issue
Patient safety is paramount to the pharmacist’s role in any healthcare setting. Included within this area is consideration of workflow, utilization of technology and pharmacy technicians, and reduction of distractions to pharmacists’ ability to provide patient care. As a recent Chicago Tribune article discusses, the current pharmacy workplace environment may not lend itself to ensure proper patient safety procedures are followed, be they based in law or internal company policies. Breaks for meals or the restroom, staffing model variations, and metric requirements are some areas of concern that may potentially impact patient safety. The proposed policy might address scope of pharmacy technician activities and technician ratios, information technology, etc. This topic will address the issue of patient safety in these areas of concern and fill in gaps within existing APhA policy to support a well-functioning, patient-centered workplace focused on patient safety.

Summary of Key Concepts

- Prescription volumes continue to increase across the United States, while pharmacy support staff levels remain relatively unchanged.
- Many state boards of pharmacy have regulations to guide lunch and rest breaks, technician ratios, and support staff activities. However, the language of these regulations may not impart a legal obligation to comply with the regulation.
- Several pharmacy organizations have published statements against the use of pharmacy metrics and prescription time guarantees. These guarantees become problematic when speed is emphasized over safety.
- Physical and environmental factors can play a major role in maintaining patient safety. These factors include the physical layout of the pharmacy, sound and lighting levels, as well as the impact of interruptions during critical tasks.
- Safety organizations have conducted medication safety self-assessments in both community and hospital pharmacies to quantify the use of safety best practices, including safe environments and manageable workloads. Conducting these may help instill a culture of safety that is open to modifying unsafe practices.
- A culture of safety also encourages error reporting through both internal and external sources. Employees should receive follow-ups after error reporting to ensure that the process is valued.
- Patient safety is impacted by the workplace of the pharmacist through several factors, including the culture, metrics, physical environment, new service requirements, and staff. A policy addressing any or all of these factors will help accomplish a pharmacists’ primary duty: keeping patients safe.
Definitions

- **Patient Safety**: Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.
- **Physical Environment**: Consists of the surroundings that can affect one or more human senses.
- **Working Conditions**: Include the physical environment, workforce staffing, workflow design, personal/social factors, and organizational factors.
- **Medication Error**: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Introduction / Background

In May 2016, the Bureau of Labor Statistics estimated there were over 305,000 pharmacists working in the United States, an 8.5% increase from 2012 when there was an estimated 281,500 pharmacists in the workforce. The data shows that 44% work in a health or personal care store, and 23% work in a hospital. Since 2012, the number of pharmacists working in health or personal care stores has increased by 9.4%, while the number of pharmacists working in hospitals has increased by 16%. There were an estimated 398,390 pharmacy technicians working in 2016, an increase of 12% from 2012. In 2016, an estimated 4.51 billion prescriptions were filled in a retail setting in the United States, a 6.4% increase from 2013. Furthermore, it is projected that retail prescriptions filled will surpass 5 billion prescriptions between 2020-2021.

While prescription volume has increased in pharmacies, pharmacists indicate that they are spending less time dispensing medications. In 2004, 48% of chain pharmacists said they work in proximity with at least one other pharmacist for the majority of the day. This percentage increased to 57% in 2014. In addition, 22% of chain pharmacists said they had help from at least 3 technicians in 2004, which remained stable at 23% in 2014. The data overall demonstrates that pharmacies are dispensing more prescriptions every year and that pharmacists are spending less time on dispensing medications and more time providing other services such as medication therapy management (MTM) or immunizations. However, there has not been a subsequent increase in the number of technicians or support staff to assist with dispensing, leaving all staff members less time to complete those tasks. Technology also needs to be considered to ensure pharmacists and technicians have an appropriate amount of time to safely process prescriptions.

In addition to increased number of prescriptions, there is also a growing concern regarding the pharmacy workplace environment in which prescriptions are processed, especially as it relates to patient safety and medication errors. Recently, an investigative article by the Chicago Tribune detailed how pharmacists missed critical medication interactions and associated these errors with workload demands placed upon the pharmacy staff. The investigative study tested 225 pharmacies in the greater Chicago area and provided reasons for the missed interactions.
including: increased speed of processing, alert fatigue, and performance metrics.\textsuperscript{5} These findings are concerning as they imply that an emphasis has been placed on speed and efficiency at the expense of accurate prescription processing. It is imperative that pharmacy work environments support appropriate prescription dispensing procedures and further improvements may help address and mitigate patient safety concerns in pharmacy practice.

**Pharmacist Workload and Workflow**

The Pharmacy Workforce Center (PWC) is a nonprofit corporation run through the American Association of Colleges of Pharmacy. Every five years, PWC conducts the National Pharmacy Workforce Study that collects data on pharmacist work activities, contributions to the workforce, work environment, and quality of work life. This survey is helpful to track current pharmacist perceptions of their work environments and allows for trends to be identified in the workplace with respect to evolving pharmacy practice.\textsuperscript{4} In 2014, the survey gathered data from 2,446 pharmacists, which was comprised of 29\% hospital pharmacists and 44\% pharmacists from chain, independent, mass merchandiser, or supermarket pharmacies. When asked to rate their workload, around 80\% of chain store pharmacists rated their workload as high or excessively high. This perception has been increasing since 2004, when around 60\% reported high or excessively high workloads. Likewise, mass merchandiser and supermarket pharmacists’ ratings of high or excessively high workloads nearly doubled between 2009 and 2014.

Next, when asked if they believed their workload had effects on various areas, nearly 45\% of all pharmacists believed their workload had negative or very negative effects on their mental health, an increase from 27\% in 2004. Approximately 28\% of all pharmacists believe that their workload has negative or very negative effects on the quality of care provided to patients, a feeling which had remained consistent from the previous 10 years. In addition, 45\% of pharmacists felt that they had so much to do that everything could not be done well, which was an increase from 33\% of pharmacists in 2004. Overall, there appears to be a trend towards demanding workloads that do not allow for thorough evaluation of prescription medications. This is concerning as increased demands on pharmacists without a subsequent increase in resources can negatively impact patient safety.

**Pharmacist Breaks and Meal Periods**

State pharmacy boards across the nation have varying degrees of regulations regarding target pharmacy workflow. These regulations may include guidelines for taking meal or rest breaks, capping pharmacist shifts each day, or even limiting the number of prescriptions a pharmacist can fill without technician assistance.\textsuperscript{6} In order to increase the likelihood that pharmacists are able to take meal and rest breaks, roughly half of the state boards of pharmacy have addressed this issue in their statutes or laws. However, it is important to notice the variation in practices between states, as well as the strength of the language. When regulations are adopted by the board, the specific words used may impact its interpretation. Much of the adopted language specifies that pharmacists “may leave the pharmacy temporarily” or “shall take a break.” However, this wording does not impart a legal obligation for pharmacists to take breaks. The only words that create a legal obligation are “must” or “must not”, and in the case of meal or rest break provisions, no current regulations use this wording.\textsuperscript{7} For example, the Arizona Board of Pharmacy “endorses and encourages pharmacy owners and managers to allow pharmacy personnel to ‘close and secure’ (in compliance with Board Rules) a pharmacy for a maximum of
thirty minutes at mid-shift, allowing personnel to relax, have a meal or otherwise occupy themselves.” This language still allows for administrators to decide if pharmacists are allowed to take a break. An excerpt from the North Carolina Board of Pharmacy reads that pharmacists working more than six hours “shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.” Businesses may have competing financial interests in mind when deciding if they will provide breaks to pharmacy staff, so boards of pharmacy may wish to consider creating stronger regulations which outline these expectations.

Within these statutes and laws, the boards of pharmacy also outline which activities are allowed to occur during a pharmacist’s brief absence. The activities allowed may significantly impact a pharmacist’s decision to take a break that is made available to them as it could negatively impact workflow if they leave the pharmacy. The majority of states that supply guidance on this topic allow technicians or interns to dispense any refill or new prescription that has already gone through final verification. Often, the pharmacist must be available for counseling at the patient’s request, or the pharmacist can be required to call the patient at another time to offer counseling. These additional requirements may discourage the pharmacist from choosing to take a break if it is provided.

Recent regulation from the Minnesota Board of Pharmacy says that a pharmacy “shall not require a pharmacist, pharmacist-intern, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required.” Other states that cap the maximum hours that employees may work include North Carolina, Virginia, and West Virginia. These limits can be important as research shows for many professions that longer shifts impact patient safety. One study compared error rates in hospital order verification by pharmacists between shifts. The first group completed a 7AM-3PM shift as a control, while a second group completed a double shift. This double shift was evaluated in two parts, the first half of a double shift from 7AM-3PM and the second half from 3PM-11PM. Out of 2000 orders processed during these shifts, errors occurred in 4.8% of the orders verified in the control group, 7% in the first half of a double shift, and 10.8% in the second half (p=0.013). These findings may indicate that more errors are made at the end of longer shifts, and that the pharmacists that complete these longer shifts may be more prone to errors at any part of that shift. While policies can help prevent individuals working longer hours, there are often exemptions and healthcare workers may still volunteer to work these longer shifts.

Pharmacy Staffing (Pharmacist-Technician Ratios, Tech-Check-Tech, etc.)
There is a fine balance in ensuring that pharmacists have adequate support from ancillary staff, such as technicians, interns, and clerks, and creating an environment that a pharmacist is able to effectively manage. To ensure pharmacists are able to sufficiently monitor all the activity that is occurring in a pharmacy, several state boards of pharmacy have instituted technician to pharmacist ratios. There is a wide variety of these ratios with nine states mandating a maximum ratio of 2:1 in both community and institutional pharmacies and up to a maximum ratio of 6:1 used in Indiana and Idaho. Moreover, 22 states have no regulations on a maximum ratio in community pharmacies, while 25 states have no regulations on a maximum ratio in institutional pharmacies. There may be benefits for the states that do utilize a maximum ratio. First, the pharmacist is not required to supervise the activity of a limitless number of staff members and can better monitor the quality of work completed. Second, if there is a need to increase staffing,
the pharmacy will first need to add another pharmacist if the maximum ratio has been met. On the other hand, these ratios may create financial issues for the pharmacy. Due to the higher cost of a pharmacist compared to a technician, a business may be less inclined or unable to add any additional staffing. Furthermore, smaller ratios may restrict scheduling and create difficulties for practice sites that do not have a stable workload.

The type of work that technicians are able to complete varies between states. When technicians are able to perform tasks that have been historically completed by a pharmacist, there may be more time for the pharmacist to complete more highly skilled activities. For example, approximately 23% of states allow technicians to assist with or complete prescription transfers in a community pharmacy. Prescription transfers are an example of an activity that often requires a significant amount of time and may limit the pharmacist from performing other tasks. In other states, technicians may also have the ability to check another technician’s work. This can be completed in a variety of ways, and 28% of state boards of pharmacy offer guidance for a “tech check tech” program within institutional pharmacy settings. For example, a pilot “tech check tech” program, focused on allowing the pharmacist additional time for patient care services in the community pharmacy setting, is being implemented in Iowa, www.iarx.org/tct. While opponents of these programs claim this increases the risks for medication errors, proponents say this is an opportunity for pharmacists to take part in more patient-centered care. Both California and Montana have released supportive statements claiming these programs will move pharmacists into more clinically focused activities that may have a positive effect on patient safety.

Pharmacy Technology
Technology used to assist with workflow in the pharmacy can include automated dispensing systems, robotics, packaging systems, central fill pharmacy sites, and drug storage systems. These technologies may assist by decreasing pharmacy workload, improving efficiencies, and reducing medication errors. One study performed in the community pharmacy setting observed more prescriptions dispensed per pharmacist full time equivalent (FTE) with use of automation technology while another demonstrated a significant reduction in observed errors with use of an automated dispensing system. Yet, other studies have demonstrated additional workflow interruptions or workarounds with use of automation technology. Use of pharmacy technology overall may aid in efficiencies within the workplace; however caution should be taken as technology may also introduce new, unforeseen sources of error.

Prescription Processing Metrics
In 2013, National Association of Board of Pharmacy (NABP) issued a position statement on the topic of performance metrics and quotas in the practice of pharmacy. NABP cited an Institute for Safe Medication Practices (ISMP) survey identifying that 83% of pharmacists believed that distractions due to metrics contributed to dispensing errors. NABP then passed a resolution to assist the state boards of pharmacy to regulate, restrict, or prohibit the use of metrics in pharmacies. Despite this, only three states were found to have specific language in their board of pharmacy regulations that control the use of metrics. A pharmacy metrics report may include scores for wait times, overall patient satisfaction, and if the prescription was ready when promised. These metrics may encourage pharmacists to rush through prescription processing to improve their wait times and patient satisfaction scores at the risk of patient safety.
Time guarantees can also introduce unnecessary risk and reduce safety. For example, Domino’s Pizza once guaranteed delivery within 30 minutes of placing an order or the order was free. They eventually dropped their guarantee after settling multiple lawsuits of injury or death due to speeding Domino’s delivery drivers.\textsuperscript{19} In the pharmacy, this additional risk is introduced when a pharmacist is pressured to complete their work quickly instead of thoroughly checking the prescription. Both pharmacy and patient safety organizations have made public statements discouraging speed as a primary marketing tool for pharmacy services. ISMP released a statement in 2011 warning that emphasizing speed in the community pharmacy can lead to errors.\textsuperscript{20} The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) released another statement in 2013 advocating for “elimination of prescription time guarantees and a strengthened focus on the clinical and safety activities of pharmacists within the community pharmacy setting”.\textsuperscript{21} In 2012, an ISMP community pharmacy survey highlighted a perceived link between time guarantees and medication errors.\textsuperscript{22} Guarantees should be discouraged as they place undue time pressures on pharmacists and technicians and do not promote safe evaluation or dispensing of the prescription.

**Physical Work Environment**

Another factor to consider in regard to patient safety is the physical work environment of the pharmacy practice site. Environmental factors such as poor lighting, interruptions, cluttered workspaces, and sound have been found to contribute to medication errors when processing prescriptions. A study performed in a community pharmacy showed that increased lighting levels were associated with a 1.2% decrease in prescription dispensing errors while another study observed a 10.7% reduction in product verification errors when pharmacists used task lights to increase illumination.\textsuperscript{23} Lighting in the pharmacy is critical to many visual tasks including the selection of prescription products, accurately interpreting handwritten prescriptions, and computer order entry. A published example described the selection of an inappropriate strength of dicyclomine due to poor lighting on the shelf where the medication was stored.\textsuperscript{24} The lighting levels needed in different areas of the pharmacy may vary; however, appropriate lighting levels should be provided to improve accuracy and reduce the potential for error.

Interruptions and distractions are common in the pharmacy practice setting and have been associated with dispensing errors.\textsuperscript{25} The process for order entry and verification are particularly susceptible to interruptions as pharmacy staff may be expected to answer phone calls, pages, or other inquiries while performing these tasks. Additionally, co-workers asking for assistance have been found to be one of the more frequent source of interruption in a pharmacy.\textsuperscript{25} Steps should be taken to minimize interruptions and distractions where possible when performing critical pharmacy tasks. Pharmacy staff members should be made aware of the impact of interruptions and distractions and trained to avoid interrupting each other with non-urgent requests. It is important also to acknowledge that pharmacy staff members may have different levels of distractibility and should be cognizant of their own need for distraction free work areas.

Sounds in the physical environment have also been attributed to medication errors and safety concerns. The Environmental Protection Agency (EPA) has recommended sound levels of 45 decibels (dB) and 35 dB at night in hospitals, however observational studies have demonstrated observed peak levels around 85-90 dB.\textsuperscript{26} For comparison, a typical conversation is around 60 dB,
a kitchen blender is 80-90 dB, and a jackhammer averages 120 dB. Sound levels louder than 85 dB may cause hearing loss with prolonged exposure. Sounds in the pharmacy work environment should be controlled to allow for accurate communication of information, and some studies have demonstrated that a lower level of ambient sound actually may improve prescription filling performance.

The physical design of the pharmacy workplace, including placement of workstations and supplies, can significantly impact the ability of staff members to accurately perform tasks. In the United Kingdom, the National Patient Safety Agency published a guidebook for the design of the community pharmacy dispensing environment. This document outlines design principles specific for pharmacy practice as they relate to the overall dispensing process. Similar principles have been employed in the United States, including using lean process improvement principles to redesign pharmacy practice sites to improve accuracy and efficiency of the dispensing process.

There are various guidance documents available that outline strategies for improving the physical work environment of the pharmacy. In 2010, the United States Pharmacopeial Convention (USP) published the General Chapter <1066> which details optimal working conditions to promote safe medication use. The chapter details specific recommendations for illumination, noise, interruptions and distractions, as well as physical design and medication safety zones. These standards were developed to address environmental factors which are some of the most commonly reported factors contributing to medication errors reported to USP. The standards are based on available research, evidence, and expert opinion and a summary of these can be found in the table below. Overall, efforts should be made to improve the physical work environment where prescriptions are processed to further reduce the possibility of medication errors reaching the patient.

Table 1: Summary of USP <1066> Physical Environments that Promote Safe Medication Use

<table>
<thead>
<tr>
<th>Description</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illumination</td>
<td>Lighting levels should be periodically measured and lighting fixtures cleaned routinely. Use fluorescent cool white deluxe lamps or compact fluorescent lamps. Illumination levels should be between 50 - 150 foot-candles (fc) or 500-1500 lux dependent upon the work performed in the area. Adjustable lighting should be provided in areas where critical tasks are performed. Lighting should be positioned to avoid glare on monitors and magnifying glasses should be provided to read small script.</td>
</tr>
<tr>
<td>Interruptions and Distractions</td>
<td>Workstations should be provided that are protected from interruptions and distractions. Visual cues may also be used to signal that an individual is completing a high risk process (e.g. a vest, outlining an area on the floor). Checklists may also be implemented to assist with focusing on the task.</td>
</tr>
<tr>
<td>Sound and Noise</td>
<td>Sound levels should be periodically measured and around 50 decibels (dBA), the level of conversation. This may be achieved by installing noise dampening materials when permitted by infection control guidelines or use of noise-cancelling headphones.</td>
</tr>
</tbody>
</table>
### Physical Design and Organization of Workspace

Countertops and fixtures should be made adjustable when possible to account for differences in height between healthcare workers and promote visibility of materials. Workspaces should be free of clutter and medications should be stored with at least 1 inch between distinct drugs.

### Medication Safety Zone

Medication safety zones include areas where critical tasks are performed (e.g., medications prescribed). In these areas, important components should be placed in convenient locations (e.g., drug information), items that are frequently used should be easily found, items that are used together should be stored together (e.g., syringes and needles), and items used in a sequence should be stored together (e.g., sterile gloves and sterile dressing kits). Also, these areas should be optimized and standardized to reflect the work performed in the area.

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**Self-Assessments and Culture of Safety**

Evaluation of patient safety at pharmacy practice sites may be accomplished through a variety of approaches including staff surveys, review of best practice guidelines, or team meetings. These methods can help provide a better understanding of the implementation of best practices and how staff members may perceive the overall safety of their pharmacy practice. Safety culture is another key component of patient safety. The Joint Commission defines safety culture as “the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization’s commitment to quality and patient safety.” Safety culture includes a transparent, non-punitive approach to error reporting which is supported by APhA policy (Medication Errors 2000). However, individuals may still feel reluctant to report errors as demonstrated in national survey data.

**Self-Assessments and Surveys**

A number of quality and safety organizations have developed tools to help assess safety practices in different practice settings. These tools are used to raise awareness of existing safety issues, identify areas for improvement, and help prioritize patient safety efforts. Some organizations also publish aggregate data for comparison, however this information should not be used to predict the safety of a practice site. Instead, the comparative data should be used to both focus and drive improvement efforts.

ISMP has published Medication Safety Self-Assessments for both hospital (2011) and community pharmacy (2017) practice settings. The pharmacy work environment is considered a key element within both assessments, which is evaluated by assessing the degree of implementation of a variety of best practices in those particular work settings (Appendix 1). These best practices include design of the workspace to provide appropriate lighting and reduce distractions as well as provisions to set limits on hours worked and provide adequate breaks. Assessments are typically completed by a team that collectively evaluates the practice setting. Graph 1 shows the implementation rate for each of the core characteristics (C1-C20) stratified by hospital bed size. Core characteristic 12 (C12) includes self-assessment on safe and effective workflows and the pharmacy’s physical environment to allow for focus on medication use without distraction. Core characteristic 13 (C13) involves self-assessment on having a well-rested staff that matches the workload without compromising patient safety. Results from the
2011 hospital self-assessment (Graph 1) indicate that survey respondents (n=1,310) demonstrated approximately 70-85% implementation with the suggested best practices in the pharmacy environment (C12 and C13). ISMP will not be collecting aggregate data for the 2017 community pharmacy assessment.

![Graph 1. Core Characteristics by Bed Size](https://www.ismp.org/selfassessments/Hospital/2011/workbook.pdf)

Source: https://www.ismp.org/selfassessments/Hospital/2011/workbook.pdf

The Agency for Healthcare Research and Quality (AHRQ) publishes surveys on patient safety culture for a variety of practice settings including both hospital and community pharmacies. These surveys evaluate how staff perceive attitudes towards patient safety at their practice sites. The surveys are administered to all staff members and scores may be compared to aggregate data published by AHRQ. Notably, findings from the 2015 community pharmacy survey indicate the greatest area for improvement was “Staffing, Work Pressure, and Pace” which received a composite 44% positive response (n=1603)(Table 2). “Staffing” was also listed as one of the areas for greatest improvement in the 2016 hospital survey (54% positive response) (n=447,584) (Table 3). “Nonpunitive Response to Error” was ranked as the greatest area for improvement in the hospital survey indicating that overall safety culture and medication error reporting are also areas requiring further assistance (Table 3).
Table 2. Community Pharmacy Patient Safety Culture Survey 2015 (n=1603)

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>% Positive Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staffing, Work Pressure, and Pace Composite</td>
<td>44%</td>
</tr>
<tr>
<td>Staff take adequate breaks during their shifts</td>
<td>68%</td>
</tr>
<tr>
<td>We feel rushed when processing prescriptions</td>
<td>21%</td>
</tr>
<tr>
<td>We have enough staff to handle the workload</td>
<td>58%</td>
</tr>
<tr>
<td>Interruptions/distractions (from phone calls, faxes, customers, etc.) in this pharmacy make it difficult for staff to work accurately.</td>
<td>31%</td>
</tr>
</tbody>
</table>

Table 3. Hospital Patient Safety Culture Survey 2016 (n=447,584) 37

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>% Positive Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staffing Composite</td>
<td>54%</td>
</tr>
<tr>
<td>We have enough staff to handle the workload</td>
<td>51%</td>
</tr>
<tr>
<td>Staff in this unit work longer hours than is best for patient care</td>
<td>50%</td>
</tr>
<tr>
<td>We use more agency/temporary staff than is best for patient care</td>
<td>65%</td>
</tr>
<tr>
<td>We work in &quot;crisis mode,&quot; trying to do too much, too quickly.</td>
<td>49%</td>
</tr>
<tr>
<td>Nonpunitive Response to Error</td>
<td>45%</td>
</tr>
<tr>
<td>Staff feel like their mistakes are held against them.</td>
<td>51%</td>
</tr>
<tr>
<td>When an event is reported, it feels like the person is being written up, not the problem.</td>
<td>48%</td>
</tr>
<tr>
<td>Staff worry that mistakes they make are kept in their personnel file.</td>
<td>37%</td>
</tr>
</tbody>
</table>

Medication Error Reporting
When the safety culture is nonpunitive, employees are more likely to voluntarily report medication errors. There are several ways to report medication errors, including both internal and external reporting. External sources include ISMP National Medication Errors Reporting Program, FDA MedWatch, USP MEDMARX®, The Joint Commission, and various state programs.38,39 The benefits of reporting errors externally include anonymity and using the error data to identify larger safety trends. Internal reporting will be specific to each business and benefits include enhanced ability to address any root causes identified in the error evaluation process. One of the top reported barriers to error reporting is lack of feedback or follow-up after reporting.40 Robust internal error reporting systems allow pharmacy staff to nonpunatively report
errors, determine their cause, and ideally prevent the error from occurring again. When error reporting is used this way, the overall culture of the business is changed to keep patient safety as the primary focus.

Conclusion
It is critically important that pharmacy work environments support best practices in patient safety and are intentionally designed to reduce the possibility of introducing errors into the medication use process. There are a variety of factors to consider when creating this practice environment including providing adequate staffing, resources, and breaks to ensure the best working environment for pharmacy staff members. As demonstrated in the research discussed, these areas continue to be a cause for concern in many practice environments and the topic of discussion across the United States. Pharmacy business models must evolve to meet changing demands of the profession; however, it is important to remember the Hippocratic Oath of “First, do no harm” when evaluating potential strategies for improvement.

References
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9. 21 NCAC 46 :2512.
11. Stimpfel AW, Sloane DM, Aiken LH. The longer the shifts for hospital nurses, the higher the levels of burnout and patient dissatisfaction. Health Aff (Millwood) 2012;31(11):2501-9.


Employment Standards Policy Statement

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.

1. APhA recognizes that the quality of a pharmacist's work-life affects public safety and that a working environment conducive to providing effective patient care is essential.
2. APhA opposes the practice of imposing minimum numbers of prescriptions which pharmacists are to dispense in a given period of time. Further, APhA opposes employment practices that evaluate a pharmacist's performance on the basis of set quotas of work performed.

2001 Work Schedules
1. APhA supports a work environment in which innovative work schedules are available to pharmacists and encourages employers to allow meal breaks and rest periods.
2. APhA encourages employers to offer benefit packages that provide dependent-care benefits, including, but not limited to, flexible spending accounts, voucher systems, referral services, on-site dependent care, and negotiated discounts for use of day care facilities, to improve workforce conditions. (JAPhA NS(5):Suppl.1:S10 September/October 2001)(Reviewed 2007)(Reviewed 2012)

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. (JAPhA 39(4): 447 July/August 1999) (Reviewed 2001) (Reviewed 2007) (JAPhA NS52(4) 458 July/August 2012)

2004 Automation and Technology in Pharmacy Practice
1. APhA supports the use of automation and technology in pharmacy practice, with pharmacists maintaining oversight of these systems.
2. APhA recommends that pharmacists and other pharmacy personnel implement policies and procedures addressing the use of technology and automation to ensure safety, accuracy, security, data integrity, and patient confidentiality.
3. APhA supports initial and ongoing system-specific education and training of all affected personnel when automation and technology are utilized in the workplace.
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 healthcare system.
6. APhA supports the elimination of hand-written prescriptions or medication orders.

2005 Patient Safety
1. Patient safety is influenced by patients, caregivers, health care providers, and health care systems.
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.

1. APhA acknowledges:
(a) Patients have the right to be informed participants in decisions related to their personal health care.
(b) Pharmacists have a professional obligation to contribute to the education of patients to help achieve optimal drug therapy.
(c) Pharmacists should provide drug related information to their patients (or patients’ agent) by face-to-face oral consultation, supplemented by written or printed material, or any other means or combination of means that is best suited to an individual patient’s needs for specific information.
2. APhA acknowledges that the pharmacist is responsible for initiating pharmacist/patient dialogue and assessing the patient’s ability to comprehend and communicate so as to optimize the patient’s understanding of and compliance with drug therapy.
3. APhA encourages the research and development of ancillary communication aids and techniques to maximize patient understanding of medication and its proper use.

2000 Medication Errors
1. APhA, as the national professional society of pharmacists, will work to ensure that pharmacy is the profession responsible for providing leadership in developing a safe, error-free medication use process.
2. APhA supports continuation and expansion of medication error reporting programs.
3. Medication error reporting programs should be non-punitive in nature and allow appropriate anonymity to facilitate error reporting and development of solutions to eliminate error.
4. APhA supports identifying the system-based causes of errors and building systems to support safe medication practice.


2001 Medication Error Reporting
1. APhA strongly encourages participation in error reporting at the organizational (pharmacy/institution) level and in other established state and national reporting programs.
2. APhA encourages direct error reporting by the individual(s) involved in the incident to ensure that the most relevant and detailed information is available for evaluation of the incident and for systems improvement.
3. Error reporting programs should regularly analyze and report information about the leading types and causes of errors reported to their system so that practitioners can utilize this information for systems enhancements and quality improvement.
4. APhA encourages state boards of pharmacy and other responsible entities to consider pharmacists participation in reporting of errors as a mitigating factor in determining any legal or disciplinary action related to the incident.


1993 Patient Counseling Environment
APhA encourages the development and use of responsible and effective design of pharmacy facilities to allow for convenient, comfortable, and private pharmacist-patient communications.


1983 Patient Medication Program
1. APhA shall strongly and actively encourage pharmacists to be available for and provide patient consultation, including written drug information, when requested or professionally appropriate.
2. APhA supports patient information programs that include reference to seeking medication information from pharmacists and does not endorse programs which, by ignoring the professional capabilities of pharmacists, may limit the patient’s ability to receive needed drug information and consultation.

Appendix 1. Environmental Factors, Workflow, and Staffing Patterns - Best Practices

Medication Safety Self Assessment for Hospitals (2011)

Core Characteristic #12: Medications are transcribed, prepared, dispensed, and administered within an efficient and safe workflow, and in a physical environment that offers adequate space and lighting and allows pharmacy staff to remain focused on medication use without distractions.

- Lighting is adequate (illumination levels around 100 foot-candles) to clearly read labels and other important drug and patient information in pharmacies, patient unit medication rooms, patient rooms, and at ADCs.
- Workspaces where medications are prepared are orderly and free of clutter.
- Pharmacies and patient unit medication rooms (or areas) have adequate space for storage of drugs, IV solutions, and drug supplies.
- Medication preparation areas in the pharmacy and on patient care units are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 decibels [dBA]).
- All phone calls to the pharmacy are triaged and forwarded to medication preparation and order entry areas only when necessary.
- Areas where drug orders are transcribed and/or entered into COMPUTER ORDER ENTRY SYSTEMS are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 dBA).
- Medication refrigerators in patient care areas are of sufficient size to allow admixtures that require refrigeration to be stored in an organized manner.
- Nurses select medications for administration in medication rooms, at ADCs, or in other areas that are isolated and relatively free of distractions, interruptions, and noise (not greater than 50 dBA).
- Practitioners who administer medications prepare and/or select one patient’s medications at a time, immediately before administering the medication.
- When new construction or renovation of an existing area where medications will be prescribed, dispensed, stored, or administered is planned, an interdisciplinary group of practicing staff involved in medication use is included in the decision-making process of the design of the area.

Scoring guideline: Choose NOT APPLICABLE if your organization has not built new space or renovated within the past 3 years.

Core Characteristic #13: The complement of qualified, well-rested pharmacy staff matches the workload without compromising patient safety.

- Medical students, medical residents, attending physicians, and other LICENSED INDEPENDENT PRACTITIONERS work no more than 24 consecutive hours, with planned protected sleep periods and naptime available. Exception: Isolated emergency situations outside of usual operations. Scoring guideline: Choose NOT APPLICABLE if your hospital does not have medical students, medical residents, or employed prescribers.
- Practitioners involved in medication use (except medical students, medical residents, attending physicians, and other LICENSED INDEPENDENT PRACTITIONERS) work no more than 12 consecutive hours. Exception: Isolated emergency situations outside of usual operations.
- Practitioners involved in the medication process have at least 10 hours of rest between shifts worked. Exception: Isolated emergency situations outside of usual operations.
Schedules and workload permit practitioners involved in the medication process to take at least one 15-minute break and one 30-minute break (for a meal) per 8 hours of work each day. Exception: Isolated emergency situations outside of usual operations.

An effective back-up plan has been established for days when staffing is short due to illness, vacation, educational absences, and fluctuations in patient acuity and workload.

Pharmacists and pharmacy technicians believe that staffing patterns in their department are adequate to provide safe pharmaceutical care on most days.

Nurses believe that staffing patterns on their units are adequate to provide safe patient care on most days.

The pharmacy department has an adequate complement of trained and dedicated personnel to meet the medication-related technology requirements (e.g., CPOE, ADCs, SMART INFUSION PUMPS, robotics, automated compounders, point-of-care bar-coding technology) of the department and organization.

The organization has an adequate complement of well-qualified and trained pharmacists to work in specialty areas or provide services to specialty populations (e.g., critical care, pediatric, neonatal, and oncology patients) that represent a substantial portion of the organization’s patient population.

The organization has an adequate complement of well-qualified and trained nurses to provide care to specialty populations (e.g., critical care, pediatric, neonatal, and oncology patients) that represent a substantial portion of the organization’s patient population.

Hospital or health-system plans for new and/or expanded clinical programs are well communicated to all affected practitioners, and appropriate consideration of resources is addressed prior to implementation so that the additional work volume will be met without compromising patient safety.

Medication Safety Self Assessment for Community/Ambulatory Pharmacy (2017)

Core Characteristic #12: Medications are transcribed, prepared, dispensed, and administered within an efficient and safe workflow, and in a physical environment that offers adequate space and lighting and allows pharmacy staff to remain focused on medication use without distractions.

- Lighting is adequate (i.e., illumination levels at least 100 foot-candles) to clearly read labels and other important drug and patient information.
- A lighted magnifying lens is in a fixed location and is used to facilitate readability of prescriptions and labels.
- The temperature and humidity in the pharmacy conform to drug storage requirements.
- The pharmacy has implemented integrated voice response (IVR) systems that are integrated with the pharmacy computer system, to triage incoming calls.
- Areas where medication orders are transcribed and/or entered into the pharmacy computer system are isolated and free of distractions and interruptions.
- Areas where medication orders are verified are isolated and free of distractions and interruptions.
- Areas where point-of-care testing and/or immunization services are provided are private and free of distractions and interruptions. Scoring guideline: Choose NOT APPLICABLE if point-of-care testing and immunization services are not provided.
- The pharmacy has a dedicated, exclusive area for general, nonsterile compounding that meets current USP <795> standards.
• The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards. Scoring guideline: Choose NOT APPLICABLE if sterile compounding is not offered.
• The pharmacy avoids using storage space that requires staff to reach over their heads or to climb to retrieve products.
• Workspaces where medications are prepared are clean, orderly, and free of clutter.
• Baskets, bins, or other containers are used during preparation and verification to separate different patients’ orders.
• The pharmacy maintains a prescription pick-up/will-call area that is free from clutter and contains enough space to prevent “spillage” into the next basket or bin.
• Plans for new and/or expanded services are well communicated to all affected personnel, and appropriate consideration of resources is addressed prior to implementation.
• The pharmacy uses an automated, off-site, centralized dispensing operation to help reduce workload in the pharmacy.
• When preparing prescriptions, pharmacy staff work with one drug product at a time and affix the label to the patient’s prescription container before working on the next prescription.
• All prescription orders (either the hard copy or a scanned image) are displayed at eye level during order entry.

Core Characteristic #13: The complement of qualified, well-rested pharmacy staff matches the workload without compromising patient safety.

• An employee assistance program is available, and participation is encouraged to help staff who are experiencing stress or issues that may affect work performance.
• Pharmacy staff undergo an annual physical examination, including vision and hearing screenings.
• Pharmacy staff work no more than 12 consecutive hours. Exception: isolated situations outside of usual operations.
• Pharmacy staff have at least 8 hours of rest between shifts worked. Exception: isolated situations outside of usual operations.
• Schedules and workload permit pharmacy staff to take at least one 15-minute break and one 30-minute break (for a meal) per 8 hours of work each day. Exception: isolated situations outside of usual operations.
• An effective back-up plan has been established for days when staffing is short due to illness, vacation, educational absences, and fluctuations in workload.
• Staffing patterns in the pharmacy are adequate to provide safe patient care services, including during times of anticipated higher workload (e.g., beginning of the month, prior to or immediately following holidays).
• When temporary agency staff are used, they have been properly oriented and trained in the particular pharmacy environment in which they will be working.
• When creating the work schedule, consideration is given to the use of supportive automated dispensing technology, prescription volume, and pharmacist/technician ratios.
• Prescription volume data is examined periodically to determine appropriate staffing levels, even during peak times when demand is highest.
• Metrics used to ascertain staff productivity and turnaround time are reasonable and do not impede the quality or safety of patient care services.
• The pharmacy does not ask pharmacists to meet a specific quota for prescription dispensing, including vaccine administrations if provided.
Use of Pharmacogenomic Data within Pharmacy Practice

The committee recommends that the Association adopt the following statements:

1. APhA emphasizes genomics as an essential aspect of pharmacy practice.  
   [Refer to Summary of Discussion Items 4.]

2. APhA recognizes pharmacists as the health care professional best suited to provide medication-related consults and services based on a patient’s genomic information. All pharmacists involved in the care of the patient should have access to relevant genomic information.  
   [Refer to Summary of Discussion Items 4, 5, 6, 7, 8.]

3. APhA supports processes to protect patient data confidentiality and opposes unethical utilization of genomic data.  
   [Refer to Summary of Discussion Items 6, 7, 9.]

4. APhA demands payers include pharmacists as eligible providers for covered genomic interpretation and related services to support sustainable models that optimize patient care and outcomes.  
   [Refer to Summary of Discussion Items 8, 10, 11.]

5. APhA urges pharmacy management system vendors to include functionality that uses established and adopted electronic health record standards for the exchange, storage, utilization, and documentation of clinically actionable genetic variations and actions taken by the pharmacist in the provision of patient care.  
   [Refer to Summary of Discussion Items 7, 12, 13, 14.]

6. APhA recommends pharmacists lead the development of evidence-based practice guidelines for pharmacogenomic and related services.  
   [Refer to Summary of Discussion Items 14, 15, 16, 17, 18.]

7. APhA advocates for the involvement of pharmacists in the development of pharmacogenomic clinical support tools and resources.  
   [Refer to Summary of Discussion Items 18, 19, 20, 21, 22.]

8. APhA encourages pharmacists to use their professional judgment and published guidelines when providing access to testing or utilizing direct to consumer genomic test results in their patient care services.  
   [Refer to Summary of Discussion Items 23.]

9. APhA urges schools and colleges of pharmacy to include clinical application of genomics as a required element of the Doctor of Pharmacy curriculum.  
   [Refer to Summary of Discussion Items 24, 25, 26, 27.]

10. APhA encourages the creation of continuing professional development and post graduate education and training programs for pharmacists in genomics and its clinical application to meet varying practice needs.  
    [Refer to Summary of Discussion Items 26, 27.]

11. APhA encourages the funding of pharmacist-led research examining the cost effectiveness of care models that utilize pharmacists providing genomic services.  
    [Refer to Summary of Discussion Items 28.]
Summary of Discussion

1. The committee discussed that in most situations a patient’s genome, for the purpose of clinical endpoints, will not change during their lifetime and it will be easier for healthcare professionals to use pharmacogenomics data proactively as more individuals obtain their genomic information.

2. The committee discussed the nature of genomic information and considered this type of information as separate and different from other health information.

3. Throughout the various policy statements, the terms genomics and pharmacogenomics are used. These terms are not interchangeable and their usage is specific to the intent of the policy statement. The committee reviewed the National Human Genome Research Institute (NHGRI) definition for genomic medicine as part of their policy development activities, “an emerging medical discipline that involves using genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use.” The committee also recognized that the practice of using genomic information within pharmacy practice goes beyond pharmaco-genes and includes such things as microbiomes, metabolomics, epigenomics, etc.

4. The committee discussed how in the interest of public safety, the focus of this topic must encompass the pharmacist, the generalist, the specialist, and the sub-specialist. The subject of genomics and pharmacogenomics is a collaborative practice area, but pharmacists should take ownership of the interpretation of pharmacogenomic data. Additionally, the utilization of genomic data supports patient safety in regards to the selection and utilization of medications.

5. The committee discussed including language around patients authorizing pharmacists to have access to their genomic information and the term “relevant” was added to clarify what information should be available to pharmacists. Additionally, genomic information would be included under provisions as part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

6. The committee recognized patient privacy concerns and how genomic and pharmacogenomics information may provide more details about a patient’s health status that is unnecessary for unfettered access to this information.

7. The committee discussed the need for a mechanism to share or access genomic data less restrictively. The committee acknowledged in the current framework, the patient is the only
member who can share information freely and agreed that this mechanism needs to change. The committee discussed how the government may be the entity capable of creating this change and it would be useful for universal standards to be created.

8. The committee discussed the creation of billing codes for genomic interpretation services. The committee recognized it will be important for pharmacists to be recognized as the providers best suited to interpret these data and be reimbursed for these services.

9. The committee reviewed the Genetic Information Non-discrimination Act (GINA) of 2008 as it relates to confidentiality of a patient’s genomic information and felt it was important to call out the unethical use of this data in a stand-alone statement.

10. The committee discussed the use of the term “using” data and how it does not describe the role of the pharmacist accurately. The committee agreed that in order for pharmacists to be recognized as leaders in this field, terms such as “interpret” or “teach” or “create” would be more appropriate.

11. The committee discussed the use of “urges”, “calls for”, and “demands” regarding payment for genomic services. The committee discussed how “demands” creates a stronger statement and is based around the need for payment to see a change in practice come to fruition. The committee also discussed how the term “demand” for statement three may create the impression that the profession is looking for benefiting itself and not patients.

12. The committee discussed the need for pharmacists’ access to genomic data and recognized that “in the provision of patient care” should be added to clarify that only those pharmacists who need access as part of patient care should obtain access. The phrase “authorized by the patient” was considered to address the concern over patient privacy and use of genomic data, however the committee agreed to select the term “relevant” to broaden this to all HIPAA-compliant situations for use of Personal Health Information (PHI) including emergencies where the patient may be unresponsive and unable to give authorization.

13. The committee discussed the need for technology to document clinically actionable genetic variation data in pharmacy practice settings as well as pharmacist-provided services.

14. The committee discussed the ability for pharmacists to order genome data. The committee recognized how whole-genome sequencing could have utility throughout the entire lifetime of a person and acknowledged that the question to answer in policy should not be whether the test should be ordered, but how the data is used.
15. The committee discussed how Clinical Pharmacogenetics Implementation Consortium (CPIC) and PharmGKB may not be the most appropriate resource for providing guidelines, because CPIC does not provide practice guidelines to meet all of the clinical practice needs. The committee agreed there is a need for a framework that various health professions can utilize for the integration of genomic data into their practices.

16. The committee reviewed existing APhA 2013, 1995 Pharmacists’ Role in the Development and Implementation of Evidence-based Clinical Guidelines policies and the committee felt strongly to call out guidelines related to pharmacogenomics in addition to these existing policies.

17. The committee discussed the need for pharmacists to lead the effort in developing guidelines. If pharmacists are to claim that they “own” pharmacogenomics, they need to take an active role in establishing the standard of care. The Committee felt that APhA should take a leadership role in achieving this activity.

18. The committee considered combining statements six and seven, but felt it was important to specifically call out the need for the development of specific evidence-based guidelines separate from tools and resources to implement the guidelines into practice. Additionally, the guidelines that are developed are to be used as standards of care for any health care professionals.

19. The committee discussed how tools and resources are already being developed, however pharmacists are not always involved in the creation process.

20. The committee discussed how clinical decision support (CDS) could be considered a tool and that clinical decision support should be based on reliable data.

21. The committee discussed the complexity of genomic data and the inability for clinical decision support to be as reliable as a pharmacist looking at raw data, especially when greater than one gene is being interpreted. The committee discussed how clinical decision support may therefore not be relevant to the pharmacists’ role and emphasized how interpreting the relevance of the alleles presented in the genomic data would be considered appropriate.

22. The committee discussed the concern that advocating for pharmacist involvement with tool development may be ahead of its time, but the committee recognized that those working in the pharmacogenomics sector now see this as a critical time to address the development of tools as commercial industries are already creating tools without pharmacist input.

23. The committee discussed subjects related to existing direct to consumer tests (i.e. 23&Me) such as who owns the data and what pharmacists can do with data from the test. The committee
recognized that pharmacists should use their clinical judgement when working with data from these tests.

24. The committee discussed the wide variation of pharmacogenomics education in schools and colleges of pharmacy. Although there is a requirement through the Accreditation Council for Pharmacy Education (ACPE) for pharmacogenomics education, the amount of pharmacogenomics education is not consistent with the needs of employers who are looking for potential employees with knowledge of pharmacogenomics. Additionally, the committee discussed the lack of education in clinical application (eg. Classroom, experiential education) of pharmacogenomics and how ACPE accreditation standards are not specific enough to address this gap.

25. The committee discussed the necessary training for student pharmacists regarding pharmacogenomics. The committee acknowledged that perhaps knowing the specific alleles is not as necessary as understanding how to interpret the information. The committee discussed how instructors of pharmacogenomics curricula should have some practice experience and not be limited to only a research background.

26. The committee discussed the potential for public education in pharmacogenomics. The committee agreed that pharmacists must be educated first before public education is addressed.

27. The committee reviewed APhA 2005, 2000 Pharmacogenomics policy as it specifically relates to statement 3 on education. The committee felt proposed statements nine and ten do not conflict with the existing policy and it was important to re-emphasize the importance of education as it relates specifically to PharmD curricula, continuing professional development, and post-grad opportunities.

28. The committee discussed the importance of clarifying research as “pharmacist-led” in order to further solidify the pharmacists’ role as leaders in pharmacogenomics. The comment was discussed that if you don’t own research, you don’t own the practice.
Use of Pharmacogenomics Data Within Pharmacy Practice

*Background Paper Prepared for the 2017-2018 APhA Policy Committee*

Jing Wu, PharmD  
2017-2018 Executive Resident  
American Pharmacists Association Foundation

### Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2017–2018 Policy Committee to recommend policy to the APhA House of Delegates related to the use of pharmacogenomic data in pharmacy practice. The Board’s guidance on this topic included, but was not limited to, the pharmacist’s role and impact on pharmacy practice models, scope of services offered, implementation challenges and opportunities, training needs for pharmacists or student pharmacists, and economic impact on the public and profession.

### Summary of Key Concepts

- The definition of pharmacogenomics (PGx), PGx data, and PGx-related terms must be clearly understood.
- The role of pharmacists and the PGx-related services they provide must be clearly defined and recognized within the profession and by other healthcare professionals.
- Pharmacists apply PGx data in current pharmacy practice models and policies, which may afford opportunities for expansion.
- A useful role for pharmacists may be interpretation and application of PGx information to patient care. Similar to other practices, pharmacist qualifications, who receives the test, when and what type of tests are ordered, safety and effectiveness assurance, who interprets, how results are managed, test duplication prevention, follow-up responsibilities, and cost should all be considered.
- Implementation challenges include research limitations, technology overload, lack of infrastructure, public perception, and issues related to privacy.
- Pharmacists and student pharmacists will likely need similar PGx training but given their distinct positions, differing teaching approaches might need to be considered to ensure adequate training.
- Policy development should incorporate careful consideration of the economic issues derived from PGx testing as they relate to individuals, populations, and the profession.
Definitions
The terms “pharmacogenomics,” personalized medicine,” and “precision medicine” are often used interchangeably, but have subtle differences that vary depending on different entities’ definitions and interpretations. According to the National Institutes of Health, National Library of Medicine, pharmacogenomics is considered part of precision medicine.\(^1\)

- “Pharmacogenomics,” is the study of how genes affect a person’s response to medications.\(^2\) As the name implies, the field combines pharmacology, the study of medications, with genomics, the study of genes and their functions. By definition of the Food and Drug Administration (FDA), PGx is defined as “the study of variations of DNA and RNA characteristics as related to drug response”; not to be mistaken for “pharmacogenetics,” or “PGt,” defined as the study of DNA sequence variations.\(^3\) PGx research involves whole genome analysis for single-nucleotide polymorphisms (SNPs) that may have associations with drug response; however, the specific function of the identified SNPs may not be specifically known.\(^4\) PGt is a subset of PGx that deals with gene-specific SNPs with known functions.\(^5\)
- “Precision Medicine,” refers to medical therapies and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.\(^6\)
- “Reactive Genomic Testing” or “Gene-Reactive Testing” refers to a single genetic test ordered on a reactionary basis as needed.\(^7\)
- “Preemptive Genomic Testing” refers to a genotyping panel of PGx variants that may be applicable for multiple medications before the information is needed.\(^8\)

For the purpose of this background paper, pharmacogenomics, or “PGx” will be the term used. The term “PGx data” will refer to the data derived from PGx or PGx tests, both gene specific and panel-based, in conjunction with medication therapy. Similar to the FDA guidance for PGx data submissions format, data will refer to raw, normalized, and gene-list classifications.\(^9\) PGx data will not refer to the use of PGx data for the purposes of biological product, proteomic, or metabolic techniques.\(^10\)

Current Pharmacogenomics Data Landscape
National Focus on PGx
The goal of PGx research is to develop personalized treatments based on genetic variant influence on drug responses that maximizes therapeutic efficacy and safety.\(^11\) The benefits of using PGx data to optimize drug therapies for individual patients is becoming increasingly evident, especially for medications with narrow therapeutic indexes or significant toxicity concerns.\(^12,13,14,15\) Though the concept of PGx first emerged in the 1950s, only recently has it been adopted by growing numbers of health care providers and applied to patient care.\(^16\)
In 2015, the launch of the Precision Medicine Initiative (PMI) by President Obama propelled broad goals of precision medicine “to enable a new era of medicine through research, technology, and policies”.17 This prompted the National Institutes of Health (NIH) to focus on the near-term goal of “precision oncology” and the long-term goal of extending research towards a wider range of disease states.18

In 2016, the NIH received a $130 million allocation to help build foundational partnerships and infrastructure for the PMI Cohort Program.19 The PMI Cohort Program, which was eventually renamed to the “All of Us” Research Program, aims to engage at least 1 million volunteers for longitudinal precision medicine research.20,21 Now the NIH moves forward with this mission to streamline health research in pursuit of more effective ways to treat disease.22

**Guidelines and Tools**

There are several PGx resources available to assist policymakers and practitioners, including pharmacists, with decisions related to PGx. The Centers for Disease Control and Prevention (CDC) Public Health Genomics Knowledge Base (PHGKB) is one critical resource for understanding PGx.23 This is an online database of resources and literature that address the translation of genomic discoveries into improved health care and disease prevention. Included in PHGKB is a Tier Table Database that contains currently available genetic and genomic tests and family health history sorted by level of evidence.24 This Tier Table Database was developed from work of the Evaluation of Genomic Applications in Practice and Prevention Working Group (EGAPP), which employed a process that intends to provide population level recommendations and required the highest level of evidence (i.e. Randomized Controlled Trials) for development. CDC also maintains a database that contains updated guidelines, policies, and recommendations on genomic research and practice.25 The contents of the guidelines database are submitted by professional organizations, federal advisory groups, expert panels, and policy groups.

Several other key guidelines and tools reflect the growth of PGx data use in the current PGx landscape:

- The Genetics/Genomics Competency (G2C2) Center provides a roadmap for recommended clinical competencies across multiple health professions, including pharmacists.26
- The American Society of Health-System Pharmacists (ASHP) has published a statement on the pharmacist’s role in clinical pharmacogenomics.27
- APhA created a 2011 white paper to outline how PGx can be applied in medication therapy management (MTM).28
- The Clinical Pharmacogenetics Implementation Consortium (CPIC) was established to create evidence-based recommendations for front-line clinicians on appropriate therapeutic interventions given available pharmacogenetic information. At present there
are 19 published guidelines, 8 of which have been recently updated. Additionally, the CPIC Informatics Group was formed in 2014 to develop recommendations for Clinical Decision Support (CDS) in Electronic Health Records (EHRs).²⁹

- PharmGKB serves as a clearinghouse for curated PGx research, guidelines (e.g., CPIC, DPWG, CPN), evidence-based PK/PD pathways for drugs, and annotated drug labels containing pharmacogenetic information approved by the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency, Japan (PMDA) and Health Canada (Santé Canada) (HCSC).³⁰,³¹,³²,³³,³⁴

Policy makers should consider these resources when deciding which specific areas they would like to make recommendations for PGx data use.

**Pharmacists’ Role and PGx Impact on Pharmacy Practice Models**

Pharmacists are anticipated to play a substantial role in PGx based on their training to assure safe and appropriate medication use.³⁵ However, the role of the pharmacist on the interprofessional team is not clearly defined.³⁶ Pharmacists’ unique role on the PGx care team should complement those of genetic counselors and other healthcare professionals as pharmacists incorporate PGx data into current pharmacy practice models.

Physicians, nurse practitioners, and physician assistants on interprofessional teams believe being able to assess and provide PGx-based treatments is necessary to optimize care; however, these prescribers also acknowledge their knowledge gap in understanding and interpreting PGx data.³⁷,³⁸,³⁹ Physicians want their PGx resources to be clinically oriented and easily accessible.⁴⁰ Nurse practitioners and physician assistants want to understand how medications prescribed using PGx data affect medication efficacy and interactions.⁴¹,⁴² As medication experts, pharmacists are well positioned to meet these needs.

**Complimentary Roles of Genetic Counselors and Pharmacists**

Pharmacists and genetic counselors may work closely on PGx care teams and any task confusion by team members can be avoided with clear delineation of their roles. The primary purpose of genetic counselors is to provide genetic disease-related pretest and posttest counseling to assist in patient care decision making.⁴³,⁴⁴ The pretest counseling includes a screening for why the patient is seeking genetic counseling and what the patient is hoping to gain from testing, a collection of the family history, an assessment of the patient’s psychosocial history, a basic genetics overview, a teaching of the patterns of genetic inheritance for the diseases the patient may be at-risk for, and a risk-benefit presentation of available tests and their limitations.⁴⁵,⁴⁶ Post-test counseling involves assisting in genetic disease result interpretation and if needed, psychosocial, social, and economic coping techniques.⁴⁷ On a clinical team, the genetic counselor is often the person to communicate PGx results to the patient for potential genetic conditions.
In contrast, the pharmacist’s role on the clinical team is related to the gene-medication relationship rather than the gene-disease relationship. The primary role of the pharmacist is to provide information on PGx test results, drug dosing, and medication selection. Additionally, pharmacists are involved in the research, evaluation, teaching, and clinical integration of PGx test results. Pharmacists have also demonstrated the ability to use PGx data to provide therapeutic recommendations in written consultations and intervene with polypharmacy patients. In PGx, the pharmacist will still play the key role of providing the right medication to the right person as part of the care team.

Whether it is PGt or PGx data that is being shared with the patient, it is important that all care team members and the patient recognize who is communicating what information, and how well each entity is understanding these communications. Examples of ways to facilitate effective communications is through a hospital pharmacy or genetics department, a patient-centered medical home model, or private contracting services that may involve catered health technologies.

**Opportunities to Contribute to Medication Optimization**

In some practice sites, PGx data has already been successfully incorporated into pharmacy practice. In health systems, pharmacists on the Pharmacy and Therapeutics (P&T) Committee and guideline panels have provided PGx input on policies and procedures related to medication use. In health information technology, pharmacists have developed guidelines for PGx integration into EHR and CDS and have assisted in developing point-of-care alerts useful for counseling patients and providing prescribing recommendations. Pharmacy residents and pharmacists have demonstrated the ability to assist with genotype-guided therapy and designing and implementing professional PGx education programs. In academic health centers and community settings, pharmacists have communicated PGx test results to patients as part of multidisciplinary teams. These examples demonstrate where pharmacist-provided PGx services can be expanded.

**PGx Testing**

Pharmacists may be well-equipped to assist in the role of ordering PGx tests given their ability to fill other provider’s PGx knowledge gap by interpreting PGx data, communicating results to patients and their care teams, and making medication recommendations to reduce current trial-and-error medication prescribing practices.

**Pharmacists Authority to Order PGx Tests:** The first consideration is whether pharmacists should have the authority to order tests. If the genetic test ordered is a whole genome test or a broad panel test, the results returned may encompass information beyond the scope of what is needed for PGx.
**Pharmacists Qualifications for Ordering PGx Tests:** The second consideration regards the level of training and experience a pharmacist needs to order a PGx test and whether this is noted by a degree, completion of a residency program, or perhaps a standardized credential. If a state does not recognize pharmacists as a provider who can order tests, some states like North Carolina passed the Pharmacy Practice Act to expand pharmacists’ scope as a Clinical Pharmacist Practitioner (CPP) to provide legal permission to do so.62

**Candidates for PGx Testing:** Widespread PGx testing has been proposed, but its clinical and economic value has yet to be discerned.63,64 PGx data provides the opportunity to gain a more holistic perspective of each patient’s disease by integrating individual gene characteristics with extrinsic and intrinsic factors. The economic and ethical discrepancies on who should be tested will be addressed in later sections of this background paper.

**Timing of PGx Testing:** Debate remains for when PGx testing should be performed for those who have not yet been tested.65 In regards to timing, there are arguments for preemptive testing versus gene-reactive testing. Preemptive testing includes a broad screening of multiple genes performed before the information may be needed so it is available at the time of test initiation. Gene reactive testing generally occurs when a specific high-risk PGx drug is being considered for treatment.66 Gene-reactive testing increases the likelihood clinicians will consider PGx results in their prescribing decisions, but this testing is only typically initiated when the clinician has substantial knowledge about gene-drug interactions and available tests. Additionally, there is increasing evidence that gene-reactive PGx tests in comparison to preemptive tests may be less cost effective in the long term and results may not be timely enough to be useful in guiding prescribing decisions.67,68,69 On the other hand, preemptive PGx testing demonstrates the potential to target the most effective treatment and to avoid specific gene-related medication adverse events.70

**Safe, Appropriate, and Effective PGx Testing:** To ensure safe and appropriate test ordering, the Agency for Healthcare Research and Quality (AHRQ) provides a toolkit for Rapid Cycle Patient Safety and Quality Improvement.71 Additionally, The CDC’s Office of Public Health Genomics (OPHG) addressed the ethics behind reliable genetic testing through the establishment and support of the ACCE Model Project from 2000 - 2004.72 The purpose of this model is to evaluate the analytic validity, clinical validity, clinical utility, and associated ethical, legal, and social implications of emerging genetic tests. This model involves collecting, evaluating, interpreting, and reporting data about genetic tests to assist policy makers in decision making. The ACCE framework remains a tool for creating regulations related to test reliability.73
Interpreting Pharmacist-Ordered PGx Test Results: In regards to who will interpret the PGx results, pharmacists routinely use their own knowledge, clinical guidelines, drug information databases, package inserts, and literature reviews to make medication-related decisions. Pharmacists may be qualified to interpret the results, but should consult other members of the health care team or refer the patient when results return highly abnormal.

Communicating and Documenting PGx Test Results: Electronic health records or online databases have been used to document and receive test results. Pharmacists have been able to fax prescribers with the patient’s genetic test result, the lab company result sheet, and recommendations. If there is no easy software redesign, leaving messages in software databases to document ordered tests has been an alternative solution used. Pharmacists must attempt to look at all sources of results and documentation prior to ordering to avoid duplication.

Follow-Up to PGx Test Results: Pharmacists who order tests must ensure there is protocol where either they themselves follow up and manage the test or an alternative option is readily available. If test results are not returned in a timely manner for a treatment decision, pharmacists may want to take the responsibility for the follow-up with either the testing laboratory or the patient to determine the necessity for reordering the PGx test.

Economic Cost of PGx Testing: The economic value of PGx testing is not clearly known because historical studies that claim economic benefit lack validity and it is difficult to capture the actual relationship between PGx testing and total costs of care at the institution or health system level. To determine the cost of either preemptive tests or gene specific tests, the best source of information would be from the laboratory testing companies or from insurance companies. For the former, it has been suggested the cost of preemptive testing focused on whole-genome testing and array-based genotyping could cost less than $1,000 per patient and would be insignificant in comparison to diagnostic and monitoring procedures. Nonetheless, laboratories bargain with Medicare contractors for prices that often reallocate in favor of the laboratory. Pharmacists may be able to connect patients to PGx tests and provide interpretation services, but these costs to the patient are typically paid out-of-pocket and thus serves as a critical barrier where the cost upfront is still perceived as expensive. It is also important to consider the relationship between testing costs and Health IT costs as it relates to the development of clinical decision support systems, additional data infrastructure, and secure data storage means.
PGx Implementation Challenges and Opportunities

For any pharmacy topic that is not well-established in practice, there will be challenges to overcome upfront that over time may lead to beneficial opportunities. The following challenges are not unique to pharmacists, but are critical for policy makers to consider in order to begin pharmacist PGx data implementation: guideline consensus based on valid evidence, integrated EHRs and functional technology to support PGx data use, and public perceptions related to privacy.

Evidence

One critical challenge for PGx data implementation is based on the inability to reach consensus on clinical guidelines and the terminology used; thus, some guidelines do not mention PGx at all. This is attributed to insufficient evidence supporting PGx-related practice benefits and because other factors may contribute to medication ineffectiveness beyond genetics. The studies that support PGx-based medication selection have varying methods, limitations, and validities. Similarly, an argument exists that no randomized controlled trials (RCTs) on PGx data use demonstrate clinical outcome improvements. Nonetheless, age, weight, gender, and disease status are considered inherent patient characteristics acceptable for dose adjustment rationale despite similar research limitations.

Pharmacists must be cautious about the idea of “genetic exceptionalism”, or the idea that genetics is entirely different than any other clinical tool they may employ and therefore must be held at different standards. Consequently, enhancing research and developing guidelines where broader consensus can be reached will be an important step to forward PGx data implementation into practice. In addition, this emphasizes the importance of advocating for more robust PGx data use research and use of well-established guidelines like those from CPIC.

Role of Technology

To help implement PGx into routine practice it is vital technology programs and systems, such as data storage and CDS tools, are in place to review complex results and to assist in accurately translating PGx data into clinically relevant information. Organizations that recognize this need include the NIH-funded Implementing Genomics in Practice (IGNITE) Network and Genomics (eMERGE) Network collaboration that created the Clinical Decision Support Knowledgebase (CDS-KB) that serves to catalog and share CDS resources for PGx program implementation. Similarly, the CPIC Informatics Working Group created recommendations for CDS implementation in EHR.

The need to support these organizations in their attempt to provide reputable CDS is only highlighted by the following challenges. Currently, PGx testing results interpreted through CDS tools can vary in quality depending on the guidelines and data they rely on. CDS tools also vary on how much detail is provided about the gene, drug-gene interaction, therapeutic implications,
clinical impact, format of interpretive data, and turn-around time. Current health system infrastructures may lack the ability to handle the large amounts of PGx data that can be generated, especially from array-based preemptive testing; therefore, workflow disruption and the use of pharmacists’ valuable time can result. As the number of genes and variants tested increase, the balance between delivering the necessary amount of detail and not overloading busy practitioners and patients with information may become increasingly difficult to attain. Consequently, it is important that practitioners are aware of limitations associated with their systems and what guidelines CDS tools rely upon.

Policy makers may want to consider recommendations that allow for resources to be easily accessible in one system and allow for easy, yet secure communication. PGx data may be most useful when integrated into electronic health records (EHRs) at the time of prescribing and dispensing. Practitioners suggest EHRs would be more useful if there was access to external PGx content and pharmacists were able to provide care using confidential health information exchanges (HIEs).

Public Perception and Issues Related to Privacy
Another key challenge for implementing PGx data is the public conversations surrounding PGx and the lack of understanding for its use. Stakeholders, including patients, practitioners and regulators, tend to have different viewpoints when it comes to issues related to privacy, cost, ownership, and test result dissemination and communication. Several of these issues may be dictated by federal or state laws and regulations, or professional standards of care.

Ethical and Social Implications - Privacy
Privacy remains one of the key issues related to the ethical and social implications of PGx testing. Despite the apparent utility and decreasing costs of next-generation sequencing (NGS) for rapid whole genome sequencing, the hesitancy to adopt preemptive testing is related to the ability of these tests to detect rare genetic variants that may be used for patient discrimination. The Genetic Information Nondiscrimination Act of 2008 (GINA) and Veterans Health Administration (VHA) Privacy Laws were created to prevent this discrimination by health insurers or employers. Even still, concerns remain for patients who apply for long-term care, disability, or life insurance. The true impact of these nondiscrimination laws on PGx-related medical practice is unclear and consent to use and to share data are yet to be established. In addition, the Health Insurance Portability and Accountability Act (HIPAA) protects patient information by requiring patient permission in order to release genetic results to third parties, including family members and health insurance companies. HIPAA remains a complex issue for certain populations without the ability to provide consent and PGx data must also be regarded in this respect.
There are other privacy considerations worth mentioning, but will not be discussed extensively based up on the scope of this paper. In research, the Common Rule, the NIH issued Certificates of Confidentiality, the Newborn Screening Saves Lives Reauthorization Act, and the NIH Genomic Data Sharing Policy each provide patient protection with their own nuances and specifications. Surreptitious DNA testing, testing without the knowledge of the person being tested, the “Combined DNA Index System (CODIS), a criminal justice database, and the Freedom of Information Act (FOIA), which provides citizens’ access to Federal documents by request, each hold their own controversial underpinnings and can be addressed when the related privacy issue arises.

Crossover Privacy and Billing
Given the longevity of PGx results, policies and regulations regarding billing for PGx data use services is also important to consider. If PGx data is available to the pharmacist and the pharmacist has proper training, it is ethical fidelity for a pharmacist to utilize this information in every encounter with a prescription. However, each of these encounters are not factored into the billing process thus far and how HIPAA would address patient permission with each encounter is also a consideration. Some noninstitutionalized providers or suppliers can use a “professional paper claim form” per the Administrative Simplification Compliance Act to bill for Medicare; however, this strategy is unlikely to be adopted because electronic claims do not qualify and often clearinghouses or other third party processors are necessary. Policies should consider both patient privacy and how to bill for PGx-related services.

Training Needs for Pharmacists and Student Pharmacists
The current knowledge gap and lack of confidence to implement PGx data is a critical reason for slow adoption in clinical practice overall. Teaching institutions recognized this and between 2005 and 2010, the addition of PGx into curricula increased by 89%. Now this number has likely increased because of 2014 updates to the Accreditation Council for Pharmacy Education (ACPE) requirements for schools and the pharmacist licensing exam. The 2016 ACPE standards state that PGx must be included as one of four factors for evidence-based clinical decision making and medication therapy management strategies. These standards encourage team-based, patient-centered care, use of EHR resources, use of clinical application, and structured institutional and professional leadership opportunities. Now that PGx is a requirement in school curricula and in licensing exams, there are opportunities to optimize pharmacists and student pharmacists training.

Student Pharmacist Education
PGx is beginning to enter the curricula of different health provider professional student programs and student pharmacists must be prepared to be a resource on their health care teams. For student pharmacists, the lack of consistency in nature, scope, curricular placement, and teaching techniques pose challenges for adequate training. The limited opportunities for students
to engage in advanced pharmacy practice experiences (APPE), residencies, and fellowships that specialize in this PGx data use also serves as a barrier. It is also important to consider interprofessional education as it relates to PGx/medication management within the health care team. Table 1 describes challenges for incorporating PGx into current pharmacy curricula.

There are strategies school administrations can employ to educate student pharmacists in PGx. First, there is an opportunity to expose students to PGx early and often, possibly during their pre-pharmacy years.\(^{133}\) Currently only 9% of pharmacy schools require genetics as a pre-pharmacy course.\(^{134}\) Second, school administration may want to ensure curricula content reflects how PGx is integrated into various areas of health including communication, management, informatics, public health, and research. Third, curricula must reflect how the practical use of PGx is impacted by genetic data sharing, laboratory test access, insurance, ethics, and socioeconomic status.\(^{135}\) Finally, student pharmacists must complete their training with a familiarity of the various roles and responsibilities different health professionals on the healthcare team will have in regards to PGx use.\(^{136,137}\)

**Current Pharmacists**

The training needs for current pharmacists will be similar to those of student pharmacists and comprehensive PGx training options must be available.

One option pharmacists can explore is to pursue a residency for additional post-graduate training specialized in PGx. St. Jude Children’s Research Hospital (St. Jude) created an ASHP-accredited postgraduate year 2 (PGY-2) experience in response to the 2011 institution-wide testing program launch that selectively migrated array-based pharmacogenetic tests into routine patient care.\(^{138,139}\) This residency program focused on teaching innovative pharmacy practice model development, translational research, and clinical informatics.\(^{140}\) Each PGY-2 graduate is expected to serve as an authoritative resource for PGx, to demonstrate leadership in the clinical field of PGx, to use evidence-based, patient-centered medication therapy, to be able to train other healthcare professionals and the public about pharmacogenetics, to conduct research related clinical PGx implementation, and to contribute to the body of knowledge for clinical PGx. One limitation to scale this residency model is that it is implemented in an academic research center with a unique population and operating model.\(^{141}\) Nonetheless, it is worth recognizing successful efforts in implementing higher level training after pharmacy school in order to make recommendations about creating more of such programs.
<table>
<thead>
<tr>
<th>Challenge</th>
<th>Recommendations</th>
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<tr>
<td>Lack of faculty with PGx practice and teaching experience</td>
<td>To increase awareness and use of resources among pharmacy educators:</td>
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<tr>
<td></td>
<td>1. Share curricula and teaching resources</td>
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<td></td>
<td>2. Expand use of train-the-trainer programs for educators</td>
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<td></td>
<td>3. Collaborate using existing resources among pharmacy educators</td>
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<tr>
<td>Limited depth and breadth of instruction</td>
<td>To allow synergistic teaching:</td>
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<tr>
<td></td>
<td>1. Develop early foundation education in PGx for pharmacy and undergraduate</td>
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<td></td>
<td>students</td>
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<td>2. Use real PGx data or create opportunity for students to use tests on</td>
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<td>themselves</td>
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<td></td>
<td>3. Develop resources for educators to implement in current coursework</td>
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<td></td>
<td>4. Incorporate non-patient care elements (test ordering and evaluation, ethical</td>
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<tr>
<td></td>
<td>issues, bioinformatics, communications) into patient cases</td>
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<tr>
<td>Inconsistent PGx implementation may affect clinical faculty expertise and</td>
<td>To increase communication, collaboration, and further development of</td>
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<td>ability for preceptor to stay current with PGx application and emerging</td>
<td>implementation practices:</td>
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<tr>
<td>literature</td>
<td>1. Teach implementation science when local implementation programs are not</td>
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<td></td>
<td>yet developed</td>
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<td></td>
<td>2. Share practice models where students can participate in clinical</td>
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<td>implementation</td>
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<td>3. Establish practitioner and faculty discussion boards or listservs</td>
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<tr>
<td>Variable needs and opportunities for practitioner education</td>
<td>To increase opportunities for further training:</td>
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<tr>
<td></td>
<td>1. Create and share resources among APPE and residency programs (sample</td>
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<tr>
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<td>syllabi, learning activities, assignments)</td>
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<tr>
<td></td>
<td>2. Develop national preceptor training programs for teaching PGx</td>
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Other options include attending live lectures, taking courses online, or engaging in PGx-specific educational programs. If a pharmacist were to take Continuing Pharmacy Education (CPE) home-study courses or attend live lectures, guidelines may be useful to ensure these teachings are comprehensive enough so that pharmacists can stay abreast of current PGx-related practices and they are capable of effectively interpreting and communicating PGx results.\textsuperscript{142,143} For example, there are “train-the-trainer” models and massive open online courses (MOOCs).\textsuperscript{144,145,146} The latter option has certain disadvantages, which must be considered for all remote easy-access programs, including a lack of instructor interaction, lack of rigor, low completion rates, difficulty assigning academic credit, and challenges for developing sound business models to provide this type of education.\textsuperscript{147} Currently, the feasibility of comprehensive programs outside of residencies is unknown, but also presents an opportunity to create programs that meet the obvious utility and demand.\textsuperscript{148} Pharmacists who provide PGx services should receive adequate training, which requires the training to be scaled up in an effective manner.

**Economic Impact on the Public and the Profession**

**Impact on the Patient/Public**

Policy makers may consider advocating for preemptive testing based upon studies that demonstrate overall cost-savings using these PGx tests. A 2017 analysis on 44 economic evaluations conducted on ten PGx-related medications in the US Food and Drug Administration (FDA) Table of Pharmacogenomic Biomarkers in Drug Labeling drew conclusions that PGx testing can be cost-effective and cost-saving, even more so if genetic information is openly available.\textsuperscript{149}

The most important cost consideration should be PGx item and services costs for the patient. Even if PGx data use is cost-saving overall, out-of-pocket upfront costs for the test may be several hundred dollars, which may be significant to the patient depending on the patient’s income.\textsuperscript{150} Some patients have health savings accounts (HSAs), but the coverage varies widely by independent plan and there is no evidence of success using these accounts.\textsuperscript{151} Pharmacists can help patients navigate the payment landscape by suggesting patients work through the laboratory test company’s billing department or consider discounts that may be available on contracted rates.

**Impact on Pharmacies and Pharmacists**

Currently Medicaid generally does not reimburse for PGx testing, but this depends on the state. Medicare Part B does reimburse for PGx testing if there is evidence to support it and the test is deemed reasonable and necessary; the cost to the patient depends on their deductible.\textsuperscript{152} Coverage by commercial private insurers is highly inconsistent, with some insurers providing full coverage and some providing none.
**Anti-Kickback Statute**

Pharmacies receive payment for medication therapy management (MTM) services and vaccinations, but other clinical services like PGx continue to face reimbursement barriers.\(^{153,154}\)

PGx tests are billed by their specific laboratory company and are done on a one-drug to one-test basis that varies greatly in terms of the gene/drug pair and the amount of reimbursement.\(^{155}\) In some cases, pharmacists obtain samples to send for laboratory testing, but this is not typically reimbursed. In other cases, pharmacies are able to expand access and be reimbursed by entering contracts with laboratories. In these situations, the Anti-Kickback Statute (AKS) is relevant for consideration.

The AKS is a criminal statute that prohibits the exchange (or offer to exchange) anything of value to induce or reward the referral of federal health care program business.\(^{156}\)

AKS establishes penalties for individuals and entities on both sides of the prohibited transaction. Therefore, even if a pharmacy does not directly bill Medicare for the test, it may be vulnerable to AKS penalties.\(^{157}\)

O’Connor et al. gave several examples of situations that describe the controversy surrounding the AKS.\(^ {62}\)

If a pharmacist recommends a patient obtain a test through their provider, the pharmacy would not be paid for this recommendation, but if they were paid, then it would be violating the AKS. If a pharmacist does not recommend a lab, but offers a related service, then the pharmacy can be reimbursed for the service without violating the law.

Pharmacists must be cautious of recommendations made by lab manufacturers where incentives may be guided by profit rather than patient care.\(^ {158}\)

If pharmacists obtain provider status through Medicare Part B, different federal concerns would need to be addressed. This background is necessary to consider how provider status policies affect billing and what recommendations pharmacists may need to avoid violation of the AKS.

**Civil Monetary Penalties Statute**

Without a robust payment model, some pharmacists provide PGx data-related services for no payment.\(^ {62}\)

In these instances, pharmacists must be aware of the Civil Monetary Penalties (MCP) Law if serving Medicare beneficiaries.\(^ {159}\)

This law prohibits the pharmacist from transferring anything of value to a Medicare beneficiary that may influence the beneficiary to order or receive a Medicare-covered item or service from the pharmacy that provided the service. This law places pharmacists in a difficult position because if pharmacists start receiving payment for their PGx services that were previously gratis, they may violate the law if they know consumer loyalty will bring the Medicare beneficiaries back to their pharmacy for their services when a cost is associated with the service. Per the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), the only exception to providing incentives to beneficiaries is when the incentive is of “nominal value”, defined as no more than $10 per item or $50 aggregate annually for any one beneficiary. The “nominal value” is based on the retail purchase price of the item, thus, whether the pharmacist violates the CMP depends on the cost of the PGx item or service.
**Payment Models**

Despite the existing barriers, pharmacies can explore models such as a cash payment model, an insurance billing model, or a modified MTM service billing model. In a cash payment model, transparency with the patient about how much each service is costs the pharmacy to deliver care is essential for sustainability.\(^{160}\) In an insurance billing model, if pharmacists achieve provider status, they could be paid underneath Medicare Part B for their services. PGx already has been billed, and still is, underneath a modified MTM service billing model through the use of current procedural terminology (CPT) codes.\(^ {161}\) The Center for Medicare and Medicaid Services (CMS) continues to gather data about which codes should be included in clinical laboratory fee schedules and what payment methods should be used to price the test codes.\(^ {162}\)

Incident-to-physician billing was historically considered a possible option for pharmacists in community and outpatient settings.\(^ {62}\) However now this payment method cannot be used by pharmacists because in order to qualify as “incident to,” services, the patient must be under a normal course of treatment that is initially performed by a practitioner that is actively involved.\(^ {163}\) Pharmacist PGx testing and services would not apply because they are not considered chronic care management and only the supervising physician or other qualified practitioner would be able to bill Medicare for the service.\(^ {164}\) Nonetheless, PGx data use provides an opportunity for public cost-savings, there are different options for patients to pay for PGx testing, and there are several models pharmacists can consider to be paid for these services.

**Conclusions**

PGx data use in the field of precision medicine provides another tool for pharmacists to improve patient outcomes. Pharmacists are well-equipped to be a resource for patients and other health providers in interpreting and understanding the data to make the best clinical decisions. As precision medicine evolves, pharmacists remain well-positioned to interpret and apply PGx information to help achieve medication optimization for all patients. Pharmacists must continue to demonstrate the utility of PGx data and develop concordant policies that support its implementation in practice.
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Relevant APhA Policies

2010 Pharmacogenomics/Personalized Medicine
1. APhA supports evidence-based personalized medicine, defined as the use of a person's clinical, genetic, genomic, and environmental information to select a medication or its dose, to choose a therapy, or to recommend preventive measures, as a means to improve patient safety and optimize health outcomes.
2. APhA promotes pharmacists as health care providers in the collection, use, interpretation, and application of pharmacogenomic data to optimize health outcomes.
3. APhA supports the development and implementation of programs, tools, and clinical guidelines that facilitate the translation and application of pharmacogenomic data into clinical practice.
4. APhA supports the inclusion of pharmacogenomic analysis in the drug development/approval and postmarketing surveillance processes.
(JAPhA NS50(4):471 July/August 2010) (Reviewed 2015)

2005, 2000 Pharmacogenomics
1. Recognizing the benefits and risks of pharmacogenomics and applications of this technology, APhA supports further research and assessment of the clinical, economic, and humanistic impact of pharmacogenomics on the health care system. This includes collaboration with other health care and consumer organizations for information sharing and development of pharmaceutical care processes involving these therapies. Pharmacogenomics is defined as the application of genomic technology in drug development and therapy.
2. APhA supports ongoing vigilance by all individuals and organizations with access to genetic information to maintain the confidentiality of the information.
3. APhA supports the development of educational materials to train and educate pharmacists, student pharmacists, pharmacy technicians, and consumers regarding pharmacogenomics.

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)
Proactive Immunization Assessment and Immunization Information Systems

The committee recommends that the Association adopt the following statements:

1. APhA supports mandatory requirements for ALL immunization providers to report pertinent immunization data into Immunization Information Systems (IIS).
   [Refer to Summary of Discussion Items 1, 2, 3, 4.]

2. APhA calls for government entities to fund enrollment and engagement of all immunization providers in Immunization Information Systems (IIS). This engagement should support lifetime tracking of immunizations for patients.
   [Refer to Summary of Discussion Items 1, 5, 6, 7, 8, 9.]

3. APhA supports nationwide integration of Immunization Information Systems (IIS) that incorporate federal, state, and local databases for the purpose of providing health care professionals with accurate and timely information to assist in clinical decision making related to immunization services.
   [Refer to Summary of Discussion Items 10, 11, 12.]

4. APhA advocates that all appropriate health care personnel involved in the patient care process have timely access to Immunization Information Systems (IIS) and other pertinent data sources to support proactive patient assessment and delivery of immunization services while maintaining confidentiality.
   [Refer to Summary of Discussion Items 3, 4, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20.]

5. APhA urges pharmacy management system vendors to include functionality that uses established and adopted electronic health record standards for the exchange of data with Immunization Information Systems (IIS).
   [Refer to Summary of Discussion Items 11, 21, 22.]
Summary of Discussion

1. The committee discussed whether vaccination reporting should be mandated across all immunization providers and not only pharmacists. The committee recognized that in several states, pharmacists are required to report to the IIS while other immunization providers are not required. Additionally, the committee discussed how one of the major barriers to IIS use is incomplete data and how incomplete data makes an IIS relatively ineffective as a screening tool.

2. The committee agreed to capitalize “ALL” to emphasize the all-encompassing nature of the statement to immunization practice.

3. The committee recognized a discrepancy between the expectation of pharmacists in some states to report the provision of an immunization into an IIS while other immunization providers are not sending information in a timely manner or at all.

4. The committee included the term “pertinent” as some IISs have data fields that are not captured by pharmacy management software systems or within the pharmacists’ patient care process. Additionally, some IISs capture inventory management data, which may not be pertinent for all vaccine providers.

5. The committee agreed that using the terminology “calls for” is stronger and more appropriate terminology than “suggests” or “advocates”.

6. The committee specifically included “lifetime tracking” to reference the importance behind including vaccine data throughout the entirety of an individual’s life rather than a discrete time point of vaccine history, such as only pediatric data.

7. The committee acknowledged that currently, state and local health departments are the main funders for IISs which led to their specific inclusion in statement two.

8. The committee discussed the barrier of financial considerations for community pharmacies to access IISs and other software programs that assist with communication between the pharmacy management system and an IIS. Additionally, the committee recognized a need for funding to onboard pharmacists into IIS and integrate IIS practices into the pharmacy workflow.

9. The committee initially discussed using the term “onboarding” and recognized the term did not encompass all aspects of funding requirements. The committee agreed to change “onboarding” to “enrollment and ongoing engagement” to reflect the need for ongoing support.
10. The committee discussed how some states have more than one IIS and a lack of communication between IISs on a local or regional level is limiting access to the most up-to-date vaccine history information. The committee discussed specifically how California has 10 systems and other states are in the development of regional IIS models. The committee agreed that multiple systems would not be an issue as long as the systems are interoperable.

11. The committee identified interoperability as an issue especially when patients cross state borders. Although states manage their own databases, it is necessary for databases to be interoperable for the most accurate vaccine history information to be available.

12. The committee referenced NABP’s *PMP Interconnect* program that allows for interoperability of PDMP networks. The committee considered a similar prospect for IIS systems to encourage sharing of pertinent IIS data.

13. The committee specifically incorporated the term “proactive” to call for immunization providers to actively assess a patient’s vaccine history consistent with CDC and the HHS-NVAC Adult Immunization Standards.

14. The committee discussed the lack of a concrete definition for the term “timely”, but felt this is the best term to use to describe the access to IIS data. The committee’s intent for including “timely” is to allow the pharmacist the ability to view a patient’s full vaccine history in order to utilize that immunization data when delivering patient care.

15. The committee discussed the need for system wide access in a timely manner to be used for proactive assessment of immunization status. The committee agreed “timely” and “proactive” were clearer in comparison to “real-time” which could indicate a sense of urgency that may not be feasible.

16. The committee recognized the lack of bidirectional access to IIS data as a barrier to implementation. After further discussion, the committee agreed that immunization data should be used to meet the intent of NVAC adult immunization standards and other guidelines.

17. The committee discussed including the term “immunization neighborhood” to include the concept of interdisciplinary care as part of a cohesive team. The committee reconsidered the use of the term “immunization neighborhood” given that the immunization neighborhood includes community leaders that do not have a need to access patient-specific vaccine information and chose instead to use the term “immunization providers” to make this distinction.
18. The committee recognized that pharmacists were not the only pharmacy staff member providing immunization services and specifically included “pharmacy personnel” to include the important role technicians, student pharmacists, and other pharmacy staff play in this process.

19. The committee discussed the issue of patient confidentiality and included the term “appropriate” when referencing pharmacy personnel to clarify that only those staff members involved in the pharmacy’s immunization delivery workflow would have access to this information.

20. The committee discussed the possibility of technician access to IIS for documentation. The committee discussed how all pharmacy personnel should have access and referenced the Walgreens model which is more efficient when pharmacy technicians assist with manual input of vaccine information into an IIS. The committee referenced how medical assistants and clerical staff in primary care settings assist with documentation and how we may capture a similar strategy.

21. The committee discussed how “interoperability standards” may refer to various coding structures such as American Society for Automation in Pharmacy (ASAP) standards or HL7. The committee agreed that those standards approved and adopted for use by electronic health records (i.e. HL7) would be the best to reference within the policy statement.

22. The committee discussed ongoing dialogue between the pharmacy profession, American Immunization Registry Association (AIRA), CDC, and pharmacy computer vendors regarding recognized standards for the transmission of immunization data between pharmacies and IIS. IISs currently utilize HL7 standards for the transmission of immunization data and are reluctant to support additional standards.

23. The committee reviewed APhA’s Guidelines for Pharmacy-Based Immunization Advocacy and Administration and recommends a review and potential revision of the content based on outcomes from the adoption of any new policy statements on this topic.
Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2017–2018 Policy Committee to recommend policy to the APhA House of Delegates related to proactive immunization assessment and utilization of immunization information systems (IIS) to improve the quality of patient care and public health. The Board’s guidance on this topic included, but was not limited to: proactive surveillance of gaps in immunizations, bidirectional and active participation in immunization information systems (IIS), inclusion of student pharmacists and pharmacy technicians in the immunization delivery process to increase immunization coverage, and improved ease of access to and use of immunization information systems (IIS).

Summary of Key Concepts

- Although more than 300,000 pharmacists are trained to provide immunizations across the lifespan, there continues to be an overall national public health need to improve low immunization rates (particularly for the adult patient population) which pharmacists can help address.
- CDC Functional Standards (and others) specify the expectation for basic IIS capabilities.
- Pharmacy dispensing systems do not interface effectively with IIS, particularly when dealing with multiple state IIS and variations in technical implementation in practice (by health departments, computer vendors and providers), despite published standards, make nation-wide standardization of an IIS difficult.
- Varying reporting and privacy requirements among states pose difficulties for pharmacists and other pharmacy personnel to utilize an IIS in day-to-day practice.
- IIS utilization and process efficiencies may increase with expanded use of non-pharmacist pharmacy personnel (i.e., student pharmacists and pharmacy technicians).
- Uncertainty of individual patient immunization status may be a barrier to timely immunization.
- Increased bidirectional use of IIS can help address the communication needs among all members of the healthcare team regarding the provision of vaccinations and related services and reduce or eliminate missed opportunities for vaccination.

Background

The Centers for Disease Control and Prevention (CDC) defines immunization information systems (IIS) – used interchangeably with “immunization registries” – as “confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.” An IIS consolidates a patient’s immunization records, helps pharmacists and other healthcare providers comprehensively assess the immunization needs of a given patient, and allows documentation of
administered vaccinations by any healthcare provider. The CDC distinguishes between benefits of IIS use at the point of clinical care versus in public health.

- At the point of clinical care, an IIS can provide a consolidated record of immunization histories from multiple providers. This record, available to relevant vaccination providers, provides clinical guidance for tasks such as recommending guideline-appropriate vaccinations.
- At the population level, an IIS provides compiled vaccination data for use in surveillance and program operations, and informs initiatives in the public health sphere that aim to improve vaccination rates and reduce vaccine-preventable disease.

For the pharmacy profession, an IIS serves as an important tool to support immunizing capabilities. In all 50 states, pharmacists are authorized to administer vaccines. More than 300,000 pharmacists are trained in immunization delivery by APhA’s Pharmacy-Based Immunization Certificate Training Program.2 86% of U.S. community pharmacies provide adult immunizations.3 Recognizing the value of an IIS, the Pharmacists’ Patient Care Process Module for Immunization Services includes utilizing IIS services as an explicit component of the initial, “Collect” phase.4 This also aligns with the HHS National Vaccine Advisory Committee (NVAC) Adult Immunization Standards that include utilization of IIS data in the assessment of immunization status, and the reporting of administered vaccines to IIS, as critical elements.

The U.S. Department of Health and Human Services’ (HHS) 2013 “State of the National Vaccine Plan”5 highlighted IISs as a key tool to ensure access and optimized use of vaccines. The report detailed HHS’ “continued support of efforts that reduce the number of ‘missed vaccination opportunities’ (e.g., those related to HPV and adolescent and adult vaccinations)…[via] Immunization Information Systems for all age groups.” Additionally, a 2012 campaign led by the National Vaccination Program Office and CDC called on pharmacists and other vaccine providers to increase vaccination rates in nontraditional settings via strategies including “linking with immunization registries” and practicing within “immunization neighborhoods.”5 Going forward, IISs are important to pharmacists for maximizing their ability to provide and administer vaccines.

The National Vaccine Advisory Committee (NVAC) 2013 revisions to the Standards for Adult Immunization Practice (https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html ) call on all healthcare professionals, regardless of whether they provide immunizations, to take steps to ensure that their adult patients are fully immunized. The new Standards are as follows:

- Assess immunization status of all patients in every clinical encounter.
- Share a strong recommendation for vaccines that patients need.
- Administer needed vaccines or refer to a provider who can immunize.
- Document vaccines administered or received by your patients.

IISs are equipped to be a solution for the assessment and documentation Standards.

Need for Immunization Information Systems (IIS)

According to a brief issued by the Infectious Diseases Society of America (IDSA) and the Robert Wood Johnson Foundation, about 40,000 to 50,000 adults in the United States die each year due to vaccine-preventable disease.11 Furthermore, a CDC Morbidity and Mortality Report (MMWR) examining 2014 vaccination data showed that annual vaccination rates declined or remained stable for every vaccine, except in Tdap for adults 19+ and herpes zoster vaccination for adults.
60+ which moderately increased.\textsuperscript{12} Vaccination rates for high risk groups and racial/ethnic disparities also did not improve. With these many missed opportunities for vaccination, the CDC pinpointed some strategies to improve coverage\textsuperscript{12}:

- assessment of patients’ vaccination indications by health care providers and routine recommendation and offer of needed vaccines to adults;
- implementation of reminder-recall systems;
- use of standing-order programs for vaccination; and
- assessment of practice-level vaccination rates with feedback to staff members.

Many of these strategies to support proactive assessment and eliminate missed opportunities can be facilitated by existing IISs. One of the Healthy People 2020 objectives (20.1) is to have at least 95% participation (two or more vaccinations) for children 6 years or younger in a fully operational population-based IIS.\textsuperscript{13}

With the retrospective analysis and forecasting capabilities associated with an IIS, pharmacists will also likely be more prepared to prevent outbreaks or effectively plan pandemic responses.\textsuperscript{41} From surveys of New York City-based immunization providers during the swine-origin influenza A (H1N1) pandemic in 2009-2010, the reporting rate of 80-85% to the Citywide Immunization Registry could have been increased due to few or no barriers to reporting to the IIS.\textsuperscript{48}

Progress (with effective utilization of an IIS in various practice settings) throughout the country is hindered by wide variation of data quality, policies in various practice regions, financial and human resource availability, and technological functionalities of an IIS (in addition to other differences).

**Immunization Information System (IIS) Prevalence and Standards**

The IIS has been present in the healthcare space for more than 20 years, having been created. However, despite best practice guidelines issued by organizations like the CDC, standardization and consistency of IISs have yet to be achieved. Health departments across most states and U.S. territories have implemented an IIS, with New Hampshire being a notable exception (although an IIS is currently under development). Complicating this landscape is the inclusion of a handful of city or region-specific IISs.\textsuperscript{9} For instance, the IIS for the San Diego area (CA), is one of ten that comprise the California Immunization Registry (CAIR).\textsuperscript{10} In contrast, the IIS for New York City is excluded from the IIS for the greater state.\textsuperscript{9}

IISs are governed by the Immunization Information Systems Support Branch (CDC/National Center for Immunization and Respiratory Disease), based on input from IIS managers and technical experts in the U.S. Specification of a “standard IIS” comes from the IIS Functional Standards (2013-2017)\textsuperscript{8} that were developed by the CDC and identify a goal for all IISs to achieve these Functional Standards by the end of 2017. These Functional Standards identify operational, programmatic, and technical capacities. The CDC defines a “fully operational” IIS as being able to “prevent duplicate vaccinations, forecast when the next dose is due, limit missed appointments, allow recall for those who missed appointments, determine when vaccines need to be repeated (i.e. evaluation), reduce vaccine waste, and reduce staff time required to produce or located vaccination records or certificates.”\textsuperscript{7} Other IIS-related standards of note include the use of Health Level Seven International (HL7) (version 2.5.1), Simple Object Access Protocol (SOAP) web services, vaccine administered (CVX)/ National Drug Code (NDC), Advisory
Committee on Immunization Practices (ACIP), and Modeling of Immunization Registry Operations (MIROW); these standards address topics such as the clinical appropriateness of immunizations, general health care standards, and guidance regarding open source tools.\textsuperscript{43}

A challenge for pharmacy is not all of these standards are commonly used or recognized within pharmacy’s current data exchange systems.

**Technology Issues**

Some technical challenges with IISs, as identified by an American Immunization Registry Association (AIRA) report in 2014\textsuperscript{14}, involve specific data points and interoperability issues. Specifically identified were the following\textsuperscript{24}:

- the quality of data;
  - AIRA characterizes “inaccurate or incomplete data” as low-quality data; conversely-complete, accurate data in an IIS-accepted format is high-quality data. Specific steps built in to current systems to ensure high-quality data include verification of correct data format and completeness of trial data submissions from providers.
- variations in patients’ names (e.g., a middle initial for one entry vs. the initial entered in same space as first name for a second entry);
- lack of patient’s address;
- inability to collect required data elements (technical obstacles or privacy limitations); and
- inability to generate file format supported by an IIS.

Some state IISs may require more information (additional fields) or information in non-HL7-compliant formats, potentially providing a disincentive for pharmacists to report to an IIS.\textsuperscript{24}

Adding to the great variability of IISs are the various reporting methods pharmacies may use to document administered vaccinations. Some common reporting methods are detailed in Table 1.
Adding to the issue is electronic health record (her)-IIS interoperability in terms of data exchange. Real-time, bidirectional data exchange is a major goal for the health information community. Ease of access; readily available, timely, and complete data; and interoperability with EHRs could provide an incentive to increase uptake of IIS reporting in pharmacy practice (potentially independent of state mandates). Definitions for various types of data exchange can be found in Table 2.

### Table 1 - Reporting Method Definitions

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HL7 Realtime</td>
<td>Each patient visit or vaccination event is transmitted to the receiving system at the time it is entered into the transmitting system.</td>
</tr>
<tr>
<td></td>
<td>- HL7 is the gold standard for IIS interfaces with external reporting capabilities, and the most common IIS interface.</td>
</tr>
<tr>
<td></td>
<td>- Metroka et.al. found that for 2014 NYC IIS reporting, HL7 reporting – versus manual data entry, and a non-standard flat file upload – from EHRs resulted in more complete and timely data.</td>
</tr>
<tr>
<td>HL7 Batch</td>
<td>Vaccination events are batched into a single HL7 file and transmitted to the receiving system at scheduled intervals (e.g. daily, weekly).</td>
</tr>
<tr>
<td>Flat File (automated)</td>
<td>Vaccination events are batched into a single flat file and transmitted through an automated service to the receiving system at scheduled intervals.</td>
</tr>
<tr>
<td>Flat File (manual load)</td>
<td>Vaccination events are batched into a single flat file (an unstructured file) and are loaded through the IIS interface using a login&gt;select file&gt;upload approach.</td>
</tr>
<tr>
<td>Facilitated Data Entry</td>
<td>Data entry is performed directly using the IIS interface through the use of newer automated tools such as driver’s license scanning and 2D bar code scanning.</td>
</tr>
<tr>
<td>Manual Data Entry</td>
<td>Data entry is performed directly using the IIS interface by logging in and manually recording the vaccination event into the IIS.</td>
</tr>
</tbody>
</table>

*Adapted from AIRA 2014 White Paper.*
Table 2 - Definitions for Types of Data Exchange

- Unidirectional – submission of data flows one direction from the pharmacy system to the IIS using either flat file or HL7 messaging formats.
- Limited Bidirectional (or Acknowledged Unidirectional) – submission flows one direction from the pharmacy system to the IIS, but the IIS provides a feedback report to the pharmacy to detail the results of the pharmacy data submission. Applies to either flat file or HL7 messaging formats. In HL7 this is the acknowledgement (ACK) response.
- Bidirectional – applies to either reciprocating unidirectional (unidirectional submissions sent from the Pharmacy to the IIS and from the IIS to the Pharmacy in an attempt to synchronize the two systems across a common patient base) or traditional query/response (queries are submitted from the pharmacy to the IIS about 1 or more patients; the IIS returns information about the patient(s) including their immunization history and possibly the forecast — in HL7 this is the QBP/RSP message pattern).
  - In other words, a bidirectional system should work in this way: a vaccination provider searches an EHR for a patient’s vaccination history, which on the backend emits a HL7 query or message. In response, a patient’s immunization history plus evaluation and decision support is returned by the IIS to the vaccination provider. The EHR should then be able to take all the information from the IIS and store it in a specific format.

Adapted from AIRA 2014 White Paper.

The CDC initiated an EHR-IIS Interoperability Project, which identified some challenges in enhancing the reporting method: readiness (of EHR, provider, and/or IIS), EHR vendor support to providers, competing priorities (such as Meaningful Use, Vaccine Tracking System (VTrckS), barcoding, Health Information Exchanges (HIEs)), and quality of the data.

The 2012 AIRA Meeting (Indian Health Service IIS profiling) and the CDC IIS Support Branch detailed the need for verification of IIS EHR-IIS bidirectional information transfer and EHR-IIS interoperability within released cooperative agreements. The most common reasons for local differences cited by a 2013 Immunization Information Systems Interoperability Status Check Report are:
- Local requirements for identifying the sender of the message;
- Inability to correctly handle vaccination refusals or history of disease;
- Rigid enforcement of minor technical requirements based on local interpretations of current or previous standards, such as HL7 (e.g. message may be rejected because ethnicity code not recognizable, or date/time end of administration field left blank); or
- Problems correctly accepting or ignoring certain types of vaccination information (e.g. status check results could not demonstrate readiness of a given IIS to receive meaningful use messages).

While bidirectional, real-time exchange is the goal, many current pharmacy management systems, because of differences in standards used for operating systems, data contained within pharmacy systems and those required by IIS, or lack of resources for making changes to current systems, require a third-party interface tool to support HL7 messaging. To address this issue, Michigan’s Lakeland Health System and Great Lakes Health Connect have taken a step toward greater interoperability by developing a state registry query function directly within Lakeland...
Health System’s EHR. Additional issues arise with receiving query responses from an IIS, as many pharmacy management systems – especially in the community pharmacy sector – do not have the technical capabilities to translate the information as a clinical management or medical record system would be able to do. The pharmacy community has continued dialogue with CDC, AIRA and the pharmacy computer vendors regarding utilizing currently operating data exchange programs (ie. Prescription Drug Monitoring Programs (PDMP)) for the data exchange. One of the major challenges is the burden on IIS to support two different standards. There is a current project involving major pharmacy computer vendors regarding the utilization of HL-7 within the pharmacist e-Care plan that could increase the use of the HL-7 standard within pharmacy. (https://www.healthit.gov/techlab/ipg/node/4/submission/1376)

Additionally, with EHR involvement, meaningful use (MU) standards come into play. MU standards encourage installation and optimal use of government-certified EHRs. Various stages of MU standard adherence have been attached to the Centers for Medicare and Medicaid Services’ (CMS) EHR Incentive Program in order to increase optimal use of EHR systems by providers and hospitals. Through three stages of MU standard adherence, ensuring adoption of certified EHRs, implementation of HL7 protocols, and a gradual push toward interoperability are goals to be reached nation-wide.

In the meantime, pharmacies are managing the submission of immunization data with various approaches identified within Table 1. Some have engaged third-party entities to serve as a conduit for the extraction of data from the pharmacy system, mapping it to data fields contained within the IIS, reporting administered immunizations and/or reporting previously administered vaccines back to the pharmacy provider. Many of these programs operate in the background and are seamless to the front-line provider. The matching of data, though, remains a challenge for these systems.

A recently published study (http://online.liebertpub.com/doi/pdfplus/10.1089/pop.2017.0049) conducted by the APhA Foundation, STC and community pharmacies in Washington State, evaluated the impact of an innovative practice model on identification of unmet vaccination needs and vaccination rates. During the study time, when patients presented for influenza vaccinations, pharmacists utilized immunization information systems (IIS) data at the point of care to identify unmet vaccination needs, educate patients, and improve vaccination rates. The main outcome measures were the number of vaccination forecast reviews, patients educated, unmet vaccination needs identified and resolved, and vaccines administered. Pharmacists reviewed vaccination forecasts generated by clinical decision-support technology based on patient information documented in the IIS. The study demonstrated that integration of streamlined principle-centered processes of care in immunization practices that allow pharmacists to utilize actionable point-of-care data resulted in identification of unmet vaccination needs, education of patients about their vaccination needs, a 41.4% increase in the number of vaccines administered, and significant improvements in routinely recommended adult vaccination rates.

Operational Challenges with Immunization Information Systems (IIS)

A 2014 AIRA White Paper examined the nature of how pharmacies are utilizing an IIS. Of 42 IIS projects in which pharmacists provided vaccinations, 36 received data from at least one pharmacy. The quality of data submitted by pharmacies received an average rating of “good” (versus excellent, fair, poor, or unknown) for accuracy, completeness, timeliness, and overall data quality. This marks an opportunity for increased institution- or organization-specific
opportunities for pharmacists regarding use of an IIS. One area of training that needs identified was adoption of immunization best practices (such as Advisory Committee on Immunization Practices (ACIP) recommendations) to ensure submission of consistently high-quality data. Sample principles from ACIP include the “internal consistency principle” – characteristics of the vaccination history should not contradict one another; this includes reported data as well as data already in the IIS – and “supremacy of medical records principle” – medical records are a more reliable source of immunization data than billing records. There are continual challenges across the health care spectrum and providers to ensuring data with EHRs is communicated to IIS, otherwise attempts to gain complete immunization histories from IIS will be hampered and of lesser value to providers. In addition, enhance communication from pharmacists to the patient’s identified primary care provider, including notification that the vaccination will be reported to IIS, could help address duplicate IIS reporting and efforts.

While IISs aim to consolidate patients’ immunization records and provide a clinical decision tool for pharmacists and other clinicians, conflicting laws and regulations may hinder the growth of IIS use. Overall, there is moderate support at the state level for operating an IIS: a 2010-11 study found 66% of states have laws explicitly authorizing IIS operations, and a 2012 CDC survey of states found 47 states automatically include minors’ immunization information without explicit parent approval. Of these 47, 11 states have mandatory participation. In addition to a lack of supportive laws and regulations, budget and human resource restrictions also contribute to system barriers.

Inconsistent reporting requirements among states is another area of improvement to address with IIS-focused policy. Voluntary reporting limits fully informed clinical decision-making and hinders public health surveillance efforts. The Idaho House of Representatives, in February 2017, voted (26-44) against legislation to mandate pharmacists reporting immunizations to the state IIS. Some rationale provided by Idaho Representatives included opposition to immunizations, concerns about data privacy, and government influence on personal health matters. In contrast, Oregon’s Board of Pharmacy and the Oregon Immunization Program (OIP) collaborated in 2014 to update pharmacy protocols to mandate pharmacist participation in the state IIS. This update increased pharmacists’ and pharmacy staff’s awareness and usage of the IIS. The Appendix includes more state-specific examples of reporting requirements and pharmacist scope of practice regarding immunizations.

AIRA and CDC established MIROW (Modeling of Immunization Registry Association in 2005 to promote “consistent operational practices across state and local IIS.” MIROW Best Practice Guidelines all had less than 30% adherence. Vaccine providers should pay attention to this low adherence: standardization and agreement upon various aspects of IISs and their use are all for naught if guidelines are not regularly used as a model and implemented. Factors that have been associated with uptake of MIROW resources are upcoming IIS platform transitions or development of provider education materials. Increasing awareness among pharmacists regarding existing IIS guidelines is certainly another opportunity to provide optimized care.

While missing vaccination opportunities increases risk of contracting vaccine-preventable diseases, over-vaccinating patients due to inaccurate IIS information or not proactively accessing the IIS increases consumer and provider healthcare costs. Overall, if a patient is unsure of
already receiving a vaccine that has no contraindications, then the recommendation is to administer that vaccine (benefit vs risk), but the CDC recognizes the potential for added healthcare costs. Therefore, the CDC has developed a deduplication toolkit to help IIS managers address duplication at the vaccine level (new administration), but also at the patient level (existing records). The vaccine-level best practices utilize MIROW recommendations. The patient-level recommendations include pursuing concerted, continuous efforts that look to utilize retrospective analyses and trends within the greater IIS community to put forth continued improvements. While deduplication efforts are highly encouraged, best practices also include emphasis on detailed documentation, development of open-source training tools and machine learning to standardize deduplication implementation steps, and the prevention of inaccurate merging of patient records. Whether deduplication efforts rely more heavily on algorithms or manual processing, consideration of appropriate incentive programs (whether formal or informal) to address the amount of work that goes into this process needs to be done.

Privacy concerns also play a role in IIS-related confusion. CDC has a mandate to ensure privacy of all users (patients and providers). For all IIS programs, a written policy detailing the following components is required. Although this policy is not required by the CDC to be shared beyond the IIS office (e.g. housed in the state’s Department of Health), many states have laws defining appropriate recipients of immunization information, opt-in/out provisions, and penalties for improper immunization information disclosure.50

- Notification – parents of minors must be notified of the existence of the IIS, what information will be contained in it, and how the information will be used.
- Choice - Parents of minors must be allowed to choose whether to participate in the IIS.
- Use of IIS information - IIS information must only be used for its intended purpose and not be used in a punitive manner.
- Access to and Disclosure of IIS information - Policies must clearly define who has access to IIS information, what constitutes a breach of confidentiality, and what the associated penalties are.
- Data Retention - the period of time that IIS information will be kept.

Among IISs, aspects that may vary include consent requirements, data access, scope of practice limitations, and data security. The large number of factors with potential variations hinder development of complete immunization records via an IIS. A 2014 Immunization Registry Operational Guidelines Evaluation Final Report found that among 44 state-based IISs, 66% enrolled adult patients with implicit consent (with an opt-out option); 18% required explicit consent (i.e. opt-in); 11% had no consent options provided; and 5% had no adult data to report. Among the pediatric population for the same group of IISs surveyed, 70% required implicit consent (opt-out); 7% explicit consent; and 23% had no consent options provided. Washington’s Department of Health delineates role-based access levels, with “only those functions necessary to conduct the user’s work.” 27 Sample available functions include:

- vaccine order status tracking
- generation of patient-specific vaccination reports (including history and forecast)
- generation of practice-based reports (e.g. practice immunization coverage data, vaccine lot data)
- vaccine ordering by State Childhood Vaccine program-enrolled providers

As pharmacists’ immunization scope of practice may increase, barriers related to current consent requirements or the misrepresentation of HIPPA requirements may prove to be limiting and need to be revised.
At the federal level, immunization reports to an IIS are exempt from the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, due to the reports’ classification as a public health activity.

Implementing and actively utilizing an IIS may interrupt daily workflow if pharmacists are unaccustomed to this practice. The Michigan Care Improvement Registry (MCIR) mandates all healthcare providers report all immunizations administered to every child younger than 20 years old within 72 hours of administration. This relatively quick turnaround helps the MCIR more closely approach a “real-time” system, allowing for multiple healthcare providers on a patient’s team to fully utilize the IIS’ vaccination forecasting capabilities. Implementation of pharmacy- or system-wide policies to promote use of an IIS would also further incentivize pharmacists to incorporate IIS-centered documentation and assessment into daily processes. However, even with mandatory reporting by numerous types of providers, across all of the states, there are still major gaps in information.

**Additional Immunization Information System (IIS) Manpower**

Beyond pharmacists, inclusion of student pharmacists and pharmacy technicians is likely to be helpful in ensuring accurate and timely documentation for the IIS, as well as wider use of the IIS by appropriately trained individuals for clinical guidance. A potential barrier in some states are laws and regulations prohibiting student pharmacists from administering vaccines, limiting the optimal utilization of a knowledgeable and capable resource. APhA policies 2005.2 (Regulation of Student Pharmacists’ Practice Experience) and 2005.1-4 (Empowerment of Pharmacists as Drug Therapy Managers, also 2003 and 1996) supports the inclusion of student pharmacists in immunization efforts and promotes immunization efforts.

Student pharmacists who have been trained in immunization delivery are a ready and willing resource to help address gaps in adult vaccination coverage, and would be of benefit to include in the conversation regarding IISs. Over the 2015-16 academic year alone, over 111,000 patients were immunized by student pharmacists (nearly 10 immunizations per student).\(^{32}\) 2016 ACPE Accreditation Standards stress the importance of preparing student pharmacists to be trained in immunization delivery,\(^{33}\) and research supports the role of student pharmacists in increasing vaccination rates and vaccine-related patient education.\(^{34,35}\)

Inclusion of pharmacy technicians may also assist in increased use of IISs. Inclusion of pharmacy technicians in immunization services has traditionally been focused on administrative assistance, such as documentation, billing, and helping report vaccine-related adverse events.\(^{37}\) The profession needs to explore ways to optimize the role of technicians within the immunization delivery process and support the pharmacists as immunization provider role. There are multiple touchpoints in the current process for pharmacy technician and other support staff to assist. Idaho is currently conducting a pilot program that includes training pharmacy technicians to administer immunizations to increase patient access to healthcare services in the pharmacy.\(^{36}\)
Further Immunization Information System (IIS) Opportunities
As of 2015, the CDC identified priorities as more efficient information exchanges among various providers, data quality, and improved functionality of existing IISs. Overall, there is a push for real-time, bidirectional information exchange with Health Information Exchanges (HIE), as no standardized “road map” is available for IIS integration with HIEs.31 Thus, bidirectional information exchanges through HIE between EHRs and IISs are rare. In addition to often conflicting privacy requirements for HIEs versus IISs, updated IIS guidelines and new IIS functionalities further complicate this situation. For example, updated accountability guidelines for providers utilizing the Vaccines for Children Program require more information compared to what is required in an IIS. Some EHRs are simply not equipped to handle that level of detail in terms of receiving and storing information that VFC requires. A work-around strategy that has been used – but could be streamlined in implementation – is having providers use an IIS web interface to enter information about doses they administered. Other providers can then send a request for information (query) to the IIS, then download the received information into their EHR. Going forward, looking for opportunities to increase facilitation of bidirectional information exchange through HIEs is needed.47

Also there is current work looking at interstate exchanges. Among 56 IISs surveyed in the 2011 IIS Annual Report (IISAR), the majority indicated no interstate exchanges. Among those that do have interstate access available, there was a further wide spectrum of authority- from specific statutes/regulations to general authority. An increased use of interstate data exchange may help address the desire for consistency and efficiency for providers who operate across state lines, such as pharmacy chains. Several pharmacy chain leaders already have multi-state IIS participation, including Walgreens (participation in 30 states), CVS (10), Rite Aid (8), Safeway (8), and Kroger (7). Most multi-state pharmacies reported electronically, while manual reporting is the preferred method for individual sites.14

Conclusion

With an increasingly interconnected world, pharmacists have a professional responsibility as public health stewards to advocate for increased vaccination coverage (per APhA policy: Empowerment of Pharmacists as Drug Therapy Managers). Advocating for organization- or institution-specific training opportunities and more external guidance documents to increase pharmacists’ familiarity and comfort with utilizing an IIS will help pharmacists deliver more comprehensive care. Pharmacists can advocate for IISs’ compliance with best practices, greater standardization among IISs, efforts to achieve EHR-IIS and pharmacy management software-IIS interoperability, and submission of high-quality data among colleagues. Student pharmacists and pharmacy technicians, with appropriate pharmacist supervision, may help accelerate adoption of IIS usage into daily workflow. As one of the most accessible health care professionals on the interprofessional team, pharmacists are positioned to champion immunization registry adoption and optimization.
References

1. https://www.cdc.gov/vaccines/programs/iis/about.html
7. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/records.html
18. Improving the Quality of Data Entering the IIS , AIRA
Related APhA Policies

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.


1997 Standards for Pharmacy-Based Immunization Advocacy
(Note: Guidelines approved by the APhA Board of Trustees in May, 1997; noted in Appendix.) APhA should adopt and disseminate standards for immunization advocacy and delivery by pharmacists.


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.

Appendix A
Per 2014 AIRA White Paper, sample state reporting requirements (to illustrate diversity of legislative and administrative guidance at the state level):\textsuperscript{14}

<table>
<thead>
<tr>
<th>State/Project Area</th>
<th>Pharmacies allowed to provide vaccination services</th>
<th>Pharmacies required to report vaccinations to the IIS</th>
<th>Jurisdiction receives data from one or more pharmacies</th>
<th>Relevant legislative and administrative references</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alaska</td>
<td>Yes</td>
<td>No*</td>
<td>Yes</td>
<td>Not provided.</td>
</tr>
<tr>
<td>Arkansas</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mandatory reporting ages 0-22 yrs. Arkansas statute applies to all immunization projects.</td>
</tr>
<tr>
<td>California</td>
<td>Yes</td>
<td>No*</td>
<td>Yes</td>
<td>Not provided.</td>
</tr>
<tr>
<td>Colorado</td>
<td>Yes</td>
<td>No*</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Connecticut</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Pharmacists in Connecticut administer to adults ages 18 and over. Current IIS is only a childhood registry.</td>
</tr>
<tr>
<td>Delaware</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Mandatory up to the age of 26.</td>
</tr>
<tr>
<td>Kansas</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Ages 6+ for influenza and 18+ for influenza and other vaccinations.</td>
</tr>
<tr>
<td>Maine</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>All reporting is optional, but if they intend to use Vaccines for Children Program (VFC) vaccine, must enroll in the IIS.</td>
</tr>
<tr>
<td>Missouri</td>
<td>Yes</td>
<td>No*</td>
<td>Yes</td>
<td>Pharmacists are required by law to report administration of vaccine to physicians. Reporting to the registry is optional.</td>
</tr>
</tbody>
</table>

\*Reporting is not mandated, but state/project does receive data from one or more pharmacies.
Required Pharmacy Reporting to an IIS

Scientific Technologies Corporation, 2016
http://ispolicy.stchome.com/
2018 House of Delegates

Report of the New Business Review Committee

Committee Members

Melissa Skelton Duke, Chair
Amber Briggs
Kisha Gant
Joey Mattingly
Haniff Sealy
Larry Selkow
Emily Willard

Ex Officio
Michael D. Hogue, Speaker of the House
NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: ____Michael Carulli, on behalf of the 2017-18 Policy Review Committee____
(Name)

____11/15/17____                                    APPhA Policy Review Committee
(Date)                                      (Organization)

Subject: Pharmacy Schools’ Curriculum and Contemporary Pharmacy Practice

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

2005, 1990  Pharmacy Schools’ Curriculum and Contemporary Pharmacy Needs

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

Background:
The needs of contemporary pharmacy practice are rapidly changing. While the committee acknowledges the good work of ACPE in its most recent standards revisions, the committee feels that the originators of this policy intended for there to be more regular, systematic and timely revision to school and college curricula than perhaps Standards might dictate. Thus, the suggested wording revision calls for schools and colleges to implement CQI processes which regularly assess the needs of contemporary pharmacy practice and make
revisions as necessary. Additionally, the committee felt this policy should support APhA providing information and resources to the individual schools to assist them in making changes and updates to their curricula based on the ever-growing practice of pharmacy. These resources can be in the form of information about current practice models, research on said practices and/or of other schools’ implementation and success of updated curricula, and ideas and ways to implement curriculum changes for the benefit of our student pharmacists and future practitioners. We believe this is consistent with the original intent of the 1990 policy (reaffirmed in 2005), and will provide clarity to the policy.

The text below shows the recommended changes and how they affect the existing policy language. New policy language is shown as underlined text and deleted language is shown struck through.

2005, 1990 Pharmacy Schools’ Curriculum and Contemporary Pharmacy Needs

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

Statement 2 of this existing policy topic will continue to be retained as it has already been approved by the APhA House of Delegates and is still relevant. For completeness sake, the second statement within this policy item states: “APhA encourages pharmacists to cooperate with schools and colleges of pharmacy by participating as preceptors and permitting their practices to be used as experiential sites.”

Current APhA Policy & Bylaws:

N/A

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

Introduced by: ___Laura Joglekar, on behalf of the 2017-18 Policy Review Committee (Name)

12/3/17 (Date) APhA Policy Review Committee (Organization)

Subject: Revisions to the Medication and Medical Device Classification System

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

2013 Revisions to the Medication and Medical Device Classification System
1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.
2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug and medical device classification system.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA’s approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA’s defined conditions of safe use.
6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA’s approved conditions of safe use.
7. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA’s defined conditions of safe use within health benefit coverage.
Background:

In certain practice settings pharmacists are qualified to provide clinical intervention as well as input in development of medications as well as medical devices, therefore the policy statement has been updated to include “medical devices”. Over the past few years, FDA is partnering with patients, healthcare professionals and industry to establish modern requirements around various devices (e.g. stents, diagnostics, point of care testing), therefore it is pertinent that APhA continues to support pharmacists who help shape FDA’s policies.

The text below shows the recommended changes and how they affect the existing policy language. New policy language is shown as underlined text and no existing language was recommended for removal.

2013 Revisions to the Medication and Medical Device Classification System

1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.

2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug and medical device classification system.

4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA’s approved conditions of safe use.

5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA’s defined conditions of safe use.

6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA’s approved conditions of safe use.

7. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA’s defined conditions of safe use within health benefit coverage.

Existing policy statements 3 and 8 within this policy topic have been recommended to be retained by the 2017-18 Policy Review Committee and therefore have not been included in this new business item.

Current APhA Policy & Bylaws:

N/A

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by:  L. Douglas Ried, PhD and Betsy M. Elswick, PharmD

(Name)

01/16/2018  Texas House Delegation and Texas Pharmacy Association

(Date)  (Organization)

Subject:  Direct and Indirect Remuneration Fees

Motion: Move to adopt the following policy statements.

1. APhA supports legislation that would prohibit retroactive direct and indirect remuneration (DIR) fees on pharmacies.

2. APhA supports prospective, transparent disclosure to pharmacies, employers and consumers, of all fee structures, performance-based network payments and penalties, and network participation requirements for any pharmacy benefit administrator.

3. APhA opposes percentage-based or flat-rate, plan-based performance assessments in lieu of assessments based on a pharmacy’s performance on pharmacy specific quality metrics.

Background:

Relatively recently, Part D plan sponsors and Pharmacy Benefit Managers (PBMs) have begun to extract DIR (Direct and Indirect Remuneration) fees from community and specialty pharmacies. At present, nearly all pharmacy DIR fees are clawed back retroactively months later rather than deducted from claims on a real-time basis which makes it extremely difficult for community pharmacists to operate their small businesses.
The "Improving Transparency and Accuracy in Medicare Part D Drug Spending Act"¹ S. 413/ H.R. 1038 will prohibit Medicare Part D plan sponsors/PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D. According to one report², the bill would:

- Lower Medicare costs for taxpayers.
- Boost transparency in drug pricing.
- Give seniors reduced cost-sharing and greater budget predictability.
- Preserve access to independent community pharmacies.
- Address the concerns of Centers for Medicare & Medicaid Services (CMS) and Medicare Payment Advisory Commission (MedPAC).

A recent OIG report documented "a sharp increase in government spending on catastrophic coverage under Medicare Part D that has coincided with the steep jump in the prevalence and magnitude of pharmacy DIR fees".³ OIG determined that these costs—borne completely by Medicare and the taxpayers who support it—have gone from $10 billion in 2010 to $33 billion in 2015. Similarly, the Medicare Payment Advisory Commission (MedPAC) has expressed concern that these post point-of-sale price adjustments shift more liability to the Medicare program and the federal government.² Moreover, most PBMs do not provide sufficient rationale for the fees. For example, approximately 67 percent of survey respondents said that PBMs provide no information as to how much and when DIR fees will be collected or assessed.⁴

The original purpose of DIRs as intended by the CMS was to lower the drug cost to the "true cost", such as including manufacturer rebates. In the case of flat fee or percentage DIRs, these are known to both parties before the transaction takes place and can be conveniently assessed at the time of the transaction. However, in other cases, even though a medication doesn't have a rebate assessed, such as on certain brand name products, pharmacies were assessed DIRs on these non-rebateable claims.⁶

In addition, a comprehensive report examining PBM DIR fees concluded that they “…have no legal basis in regulation and may, in fact, violate certain laws”.⁵ Examples of regulatory and statutory violations may include the Administrative Procedure Act, the Federal Any Willing Provider Law and the Federal Prompt Payment Law.

Moreover, DIR fees on pharmacies do not reduce the cost of drugs for beneficiaries at the point of sale and in fact push seniors into the 'donut hole' or catastrophic phase of the Part D benefit faster. Patients pay the higher prescription cost. If the cost was determined in real time, the savings that is clawed back from the pharmacy would be passed on to the patient and it would take longer for the patients’ expenditures to reach the donut hole levels. Instead, the savings are retained by the PBM ostensibly to offset higher premiums. However, in evaluating the impact of HR 1038/S 413, the Wakely Consulting Group concluded that any minor increase in beneficiary premiums would be largely offset by out-of-pocket savings at the pharmacy counter (i.e., 0.15 percent per year or a 1.5 percent increase in net costs over the course of 10 years).⁷
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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Mary Elizabeth Bradley, PharmD Candidate 2018

01/04/2018

APhA Academy of Student Pharmacists

Subject: Efforts to Reduce Mental Health Stigma

Motion: Move that APhA adopt the following policy statements:

1. APhA encourages all stakeholders to develop and adopt evidence-based approaches in order to educate the public and reduce mental health stigma. This may include, but is not limited to, depression, bipolar disorder, schizophrenia, anxiety, and other disorders and conditions.

2. APhA supports the increased utilization of pharmacists and student pharmacists with appropriate training to actively participate in psychiatric interprofessional health care teams in all practice settings.

3. APhA supports the inclusion and expansion of mental health education and training in the curriculum of all schools and colleges of pharmacy and post-graduate opportunities.

Background:

As the prevalence of mental disorders continues to increase worldwide, the mental health community remains an underserved and undertreated population. Although approximately 1 in 5 adults in the United States (43.8 million, or 18.5%) suffers from mental illness in a given year, only 41% of adults in the United States with a mental health condition have received mental health services in the past year.\(^1\) Health care providers must have a greater commitment towards educating the public on mental health disorders, including but not limited to risk factors, signs and symptoms, when and where to seek medical attention, and the safe and proper use of medications. As the most accessible health professional, pharmacists are uniquely positioned to play a greater and more patient-centered role in the delivery of mental health services.

With the 21st Century Cures Act being the largest piece of mental health legislation passed since 2008, the shortage of mental health services is more apparent now than ever.\(^2\) As the pharmacotherapy experts, pharmacists’ knowledge and skills can be leveraged to increase access to mental health services in both the inpatient and outpatient settings. The most important skills pharmacists must exhibit are compassion, communication, and patient-centered care. Furthermore, pharmacotherapy is a predominant part of the treatment of mental disorders and conditions. Patient response to medication is variable and often
requires careful consideration of patient characteristics, preferences, and the medication side effect profiles. As such, pharmacists can aid in medication selection based on patient characteristics, monitor for efficacy and safety, titrate medications to optimize patient response, and encourage medication adherence through patient counseling.

Beyond medication reviews and patient education, pharmacists can perform screening and risk assessment services, in addition to referring patients to an appropriate provider. The impact of the aforementioned pharmacist-driven services in mental health is demonstrated by a study from Wang and colleagues in a Los Angeles safety-net clinic. Researchers documented clinically significant improvements where 77% of patients showed improvement from baseline. The APhA Foundation’s Project ImPACT: Depression further illustrates pharmacists’ impact on mental health care. Patients that enrolled and stayed in the employer-sponsored treatment study had noteworthy improvements in their Patient Health Questionnaire-9 (PHQ-9) score. The PHQ-9 is a validated, self-administered depression assessment tool which was administered by pharmacy care managers at baseline and subsequent follow-up visits during the study. Notable results include 83% of patients with severe depression at baseline achieved remission, which is defined as a PHQ-9 score less than 5, and 68% of patients had a 50% reduction in their PHQ-9 score. Not only do the pharmacist-led services increase rates of adherence and improve patient satisfaction, but they can also have a significant financial impact. One study reported an estimated cost savings of approximately $22,000 during a 15-month trial period when a psychiatric pharmacist was involved in the pharmaceutical care in a low-income setting. These are examples of the many evidence-based studies that show how valuable a pharmacist can be in improving access to mental health services.

Nonetheless, a growing body of evidence suggests that mental health professionals are a primary source of stigmatizing attitudes and behaviors. Although some studies have found pharmacists to have generally favorable attitudes towards people with mental disorders, international data from a six-country study shows suboptimal attitudes toward people with schizophrenia and severe depression were common among student pharmacists. Furthermore, pharmacists have reported being uncomfortable discussing symptoms of mental disorders and felt they were less likely to follow up with patients who have a mental disorder than with those who have a cardiovascular illness. As pharmacists interact with patients who have mental disorders on a regular basis, this professional culture has significant implications, such as social marginalization and non-adherence. The aforementioned attitudes towards mental disorders, and a lack of confidence to provide pharmacy services to patients with mental disorders, underscore the need for pharmacy education reform as it relates to mental health.

Additional training within pharmacy school curriculum and post-graduate training programs will improve pharmacists’ and student pharmacists’ comfort level when speaking to patients about mental health. Given the predicted increase of clinical pharmacy outpatient positions in the future, pharmacists will likely be managing medications for most chronic conditions, including mental health disorders. Thus, it is vital that student pharmacists are aware of the increasing need to care for patients with mental illnesses. Pharmacy curriculum and training must complement the traditional focus on pharmacotherapy by adopting evidence-based approaches to reduce mental health stigma. Student pharmacists have begun addressing this matter through extracurricular efforts. For example, the Samford University McWhorter School of Pharmacy APhA-ASP Chapter created Operation Mental Health, which added depression screenings and mental health public health awareness material to their health screenings. The University of Texas at Austin College of Pharmacy APhA-ASP Chapter started Operation Brain, which focuses on mental health by working closely with a local women’s shelter. As educational programming for pharmacists and student pharmacists alike are improved, pharmacists will be better positioned to provide care for their patients with mental disorders.
References:

Current APhA Policy & Bylaws:

2004, 1965  Mental Health Programs

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


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

Introduced by: _____ Betsy Elswick and L Douglas Reid _________
(Name)

1/26/2018 _____ Texas House Delegation and Texas Pharmacy Association
(Date) (Organization)

Subject: Pharmacist’s permissive language related to medication cost

Motion: Move to adopt the following policy statement:

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

Background:
On October 17, 2017, Thomas Menighan, Executive Vice President and Chief Executive Officer of the American Pharmacists Association, provided testimony before the U.S. Senate Committee on health, Education, Labor & Pensions. In his remarks, Mr. Menighan stated:

“As the organization representing pharmacists in all practice settings, APhA has been, and is, a strong supporter of policies which increase patients’ access to affordable and cost-effective medicines. Decisions along the entire drug supply chain impact patients’ medication costs, including arrangements between manufacturers, wholesalers, insurers, and pharmacy benefit managers, or PBMs. Because of these upstream stakeholder policies, for most patients, pharmacists have limited options to impact patients’ final drug costs.”

Pharmacists increasingly cite concerns about contractual agreements that prohibit them about speaking to their patients about the out-of-pocket cost of a drug versus a health carrier’s reimbursement rates. Effective October 1, 2017, the state of Connecticut passed Senate Bill 45 pertaining to contracts between a pharmacy and a pharmacy benefits manager. This legislation was enacted to provide permissive, non-punitive language to
allow pharmacists to disclose information related to the costs of medications to their patients/purchasers. The language does NOT require cost information to be disseminated. Rather, it leaves the communication at the pharmacist’s discretion to assist patients in making informed decisions about their health care.

According to Connecticut’s recently enacted legislation:

“On and after October 1, 2017, no contract entered into between a health care provider, or any agent or vendor retained by the health care provider to provide data or analytical service to evaluate and manage health care services provided to the health carrier’s plan participants, and a health carrier shall contain a provision prohibiting disclosure of (1) billed or allowed amounts, reimbursement rates or out-of-pocket costs, or (2) any data to the all-payer claims database program established under section 38a-1091. Information described in subdivisions (1) and (2) of this subsection may be sued to assist consumers and institutional purchasers in making informed decisions regarding their health care and informed choices among health care providers and allow comparisons between prices paid by various health carriers to health care providers.”

In addition to Connecticut, there are currently four other states (Georgia, Louisiana, Maine, and North Dakota) who have passed similar legislation that forbid PBMs from including in contractual agreements wording / language that prohibits the pharmacist from disclosing when out-of-pocket costs for a medication may be less than the traditional copayment. Maryland is also currently considering passing similar legislation.

While APhA has policy related to the access to and affordability of medications to patients, policy does not exist related to so-called “gag orders” that restrict the pharmacist from voluntarily communicating cost information with the patient or purchaser of prescription medications. This additional proposed policy statement would strengthen APhA’s ability to advocate for our patients’ access to affordable medications and provide statements that serve to protect pharmacists in their ability to communicate fully with their patients. (See addendum of Menighan’s testimony for APhA House of Delegates Policy Statements Related to Drug Pricing.)

Sources:
Current APhA Policy & Bylaws:

2013, 2001, 1994 Pharmacist-Patient-Prescriber-Payer Responsibilities in Appropriate Drug Use

1. APhA advocates the following guidelines for pharmacist-patient-prescriber-payer responsibilities in appropriate drug use:

(a) Pharmacists’ Responsibilities

○ Serve as a drug information resource;
○ Provide primary care;
○ Collaborate with the prescriber and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
○ Identify formulary or generic products as a means to reduce costs;
○ Intervene on behalf of the patient to identify alternate therapies;
○ Educate the patient about the treatment regimen and expectations, and verify the patient’s understanding;
○ Identify, prevent, resolve, and report drug-related problems;
○ Document and communicate pharmaceutical care activities;
○ Monitor drug therapy in collaboration with the patient and prescriber to ensure compliance and assess therapeutic outcomes;
○ Maintain an accurate and efficient drug distribution system; and
○ Maintain proficiency through continuing education.

(b) Patients’ Responsibilities

○ Assume a responsibility for wellness;
○ Understand the coverage policies of their benefit plan;
○ Share complete information with providers, including demographics and payment mechanism(s);
○ Share complete information regarding medical history, lifestyle, diet, use of prescription and over-the-counter medications, and other substances;
○ Participate in the design of the treatment regimen;
○ Understand the treatment regimen and expected outcomes;
○ Adhere to the treatment regimen; and
○ Alert prescribers and pharmacists to possible drug-related problems or changes in health status.

(c) Prescribers’ Responsibilities

○ Assess and diagnose the patient;
○ Share pertinent information in collaboration with the pharmacist and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
○ Clearly communicate the treatment plan and its intended outcomes to the patient directly or in collaboration with the pharmacist;
○ Remain alert to the possible occurrence of drug-related problems and initiate needed changes in therapy;
○ Collaborate with the patient and the pharmacist in drug therapy monitoring; and
○ Maintain proficiency through continuing medical education.

(d) Payers’ Responsibilities

○ Determine the objectives and desired benefits of pharmacy service;
○ Design the coverage with patient and provider input using products and services to produce beneficial outcomes;
○ Contract with providers on the basis of outcomes and efficient use of resources;
○ Adopt efficient, clear, and uniform administrative processes;
○ Communicate requirements of compensation for levels of care;
○ Educate patients and providers about current eligibility and benefit information;
○ Expediently process payments; and
○ Be responsive to advances in contemporary practice.


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

Introduced by:  _____ Carmela Silvestri PharmD
(Name)

2/13/2018          New Jersey Pharmacists Association
(Date)              (Organization)

Subject: Gluten Content and Labeling in Medications

Motion: Move to adopt the following policy statements:

1. APhA supports labeling of all prescription and over the counter medications that indicates the presence or absence of gluten (protein associated with wheat, barley, rye or their derivatives) regardless of whether the addition of these substances is intentional or inadvertent.
2. APhA supports required gluten status verification for all plant derived excipients used in the manufacture of medications to assure that no cross-contamination has occurred, and in the absence of this verification, that batch testing of medication products be required to determine if they are free of detectable gluten.
3. APhA encourages the FDA to require post manufacturing testing of gluten content in oral drug products, and making quantitative information on gluten content easily accessible to health professionals.
4. APhA encourages USP to develop assays that can accurately detect trace levels of gluten in finished drug products and set appropriate standards
5. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.
6. APhA supports a mechanism for third party payers to acknowledge the need for, and accept responsibility for providing access to, medications with no detectable gluten when medically necessary.
7. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it relates to medication absorption.
8. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.

Background:
Supporting statements

1. Several studies have been done to estimate the time required by pharmacists in determining the gluten status in medications in order to protect patients from exposure. The celiac community is riddled with anecdotal stories of patients who report being left to check with manufacturers on their own to verify gluten status of their...
medications. This is presumably because of the uncompensated time burden on pharmacies associated with calling manufacturers with each prescription to determine gluten content. To compound the problem, not all drug manufacturers are able to provide information on excipients and those who can, may change their sources at any time—without informing the patient or pharmacy. Manufacturer information contacts are not available during all pharmacy hours when this information is needed. Drug product information specialists may need to research the gluten status before responding. Ingredients derived from wheat, barley or rye include Modified starch (source not specified), Pregelatinized starch (source not specified), Pregelatinized modified starch (source not specified), Dextrates (source not specified), Dextrin (source not specified but usually corn or potato), Dextrimaltose (when barley malt is used), Caramel coloring (when barley malt is used). Pharmacists may not recognize these as gluten sources. Frequently the response from manufacturers is that no gluten containing ingredients are used in the manufacturing process but that the company acknowledges that they cannot verify that the final product is gluten free.

2. It is generally accepted that grains such as oats and dried legumes are subject to cross contamination as a result of crop rotation, farming equipment and shared processing facilities. Untested foods, which would normally be considered allergen free, are frequently labeled to inform more sensitive consumers of the risk of cross contamination. These labels may take the form of the statement: “made in a facility that also processes wheat”. This labeling is voluntary in the Food Allergen Labeling and Consumer Protection Act (FALCPA). This information would be useful in excipients used in production of medications as it would indicate a need for additional determination of purity. Although use of GMPs may preclude contamination in the drug manufacturing process, this is not the case for excipients processed as foods (for which labeling of gluten content is voluntary).

3. Symptoms associated with celiac disease may be intestinal or extra-intestinal. Clinical intestinal symptoms include diarrhea, flatulence, severe stomach pain, weakness and fatigue. Extra intestinal symptoms are multi-systemic and may include neurologic symptoms such as paresthesia, migraine, and seizure and hormonal abnormalities such as amenorrhea, infertility and impotence. Continued exposure can lead to osteopenia, anemia, prothrombin deficiency, failure to thrive and growth retardation associated with malabsorption syndrome. An increased risk of gastric malignancies and B-Cell and T-cell lymphoma is seen. Research has shown that the threshold for symptoms resulting from gluten exposure is subject to significant patient variability. It is important to note that it has been estimated that up to 70% of patients with celiac disease do not report any clinical symptoms. These asymptomatic patients have no outward signs to indicate they have experienced stimulation of the autoimmune response and will experience disease-associated intestinal damage with continued exposure. In addition, up to 6 percent of the population suffers from non-celiac gluten sensitivity (NCGS) resulting in varying degrees of clinical illness as a result of gluten exposure without evidence of intestinal autoimmune damage. Standards for labeling of finished products would guarantee that patients are not exposed without their knowledge. If all products are tested, the noting of the presence of detectable gluten content on labels would allow patients, along with their pharmacist/physician, to evaluate the risk/benefit of treatment. Easily retrievable information on gluten content in products would allow a pharmacist to identify products with lower content when trace gluten exposure cannot be avoided.

4. The definition of the terminology “gluten free” was regulated in food products in 2014 as a voluntary labeling standard. The standard of 20ppm was chosen as the lowest level detectable using available technology at that time. It is now possible through Elisa testing to determine levels of intact proteins as low as 5ppm and protein fragments at 10ppm. Studies are needed to determine if peptide fragments with single receptor sites can cause as much damage as complete proteins. The Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten (May 2011) conducted by Office of Food Safety Center of Food Safety and Applied Nutrition Food and Drug Administration stated that repeated (sub-chronic) exposure of 0.4mg/day of gluten was shown to produce morphological changes in diagnosed celiac patients. FDA also determined in this report that a single exposure of 0.015mg could cause clinical symptoms in patients. Establishment of any “acceptable” gluten level in medications would need to account for regimens that require ingestion of multiple units such as dosing of 3-4 dosage units per day, as well as, the combined effect of multiple medications used in combination to treat one or more chronic disease. To
eliminate the risk of medications causing damage to susceptible patients, gluten content may need <1ppm. Since we do not currently have an assay designed for drug testing to determine trace amounts, we feel that APhA should encourage USP to develop testing methods that would allow the industry standard to be established at a level that would truly protect these patients.

5. An obvious solution to the problem of gluten exposure is the elimination of known sources of gluten that cannot be refined to a level that would be safe. Encouraging manufacturers to eliminate these excipients in their products moving forward would be helpful. Full disclosure of the inclusion of any known gluten source is essential to patient safety but currently not regulated.

6. Celiac patients who experience clinical adverse effects from a gluten contaminated medication product may either incorrectly attribute the symptoms to the active drug ingredient (assuming the medication to be unacceptable) or refuse treatment altogether. Treatment refusal can lead to worsening disease, hospitalization and additional cost and adverse effects on quality of life. Since complete abstinence from ingested gluten is the only treatment for celiac disease, third party payers need to bear the responsibility for ensuring that medication used to treat a different illness does not aggravate celiac autoimmune disease.

7. Celiac disease related malabsorption could necessitate changes in oral dosing, and adjustment as intestinal healing occurs. Research into the implications of the effects on medication absorption could allow pharmacists and prescribers to better manage these patients.

8. Pharmacists need to be aware of celiac disease and gluten sensitivity in order to guide patients to verified gluten-free products and assist in limiting inadvertent exposure.

**Why this is important?**

Approximately 1% of the population or 3 million Americans have celiac disease. Celiac disease is diagnosed endoscopically when changes in intestinal morphology due to inflammatory autoimmune damage are found. These changes are the result of exposure to gluten, which is defined as the proteins found in wheat, barley, rye, and most of their derivatives. Although celiac autoimmune stimulation has been known to result in multisystem damage, no absolute safe threshold for stimulation of the autoimmune response has been established due to heightened sensitivity in some patients. Some celiac patients may be unable to tolerate even trace exposure.

The estimate of 3 million people with celiac disease in the US may be conservative. Less than half experience the clinical symptoms that would cause them to seek a diagnosis until malabsorption complications are experienced. Asymptomatic patients are diagnosed based on family screening and based on results of endoscopy performed for other reasons. Celiac related malabsorption has been linked to several forms of anemia, vitamin K deficiency coagulation abnormalities, osteopenia, and growth disruption, weight loss and failure to thrive in children. The genetic predisposition is shared by 40% of the general population and is common to all celiac patients, but the trigger to active disease is still subject to speculation. The medical community is slow to suspect celiac disease in adult patients and it takes an average of 4-8 symptomatic years before being correctly diagnosed.

In 2011, the Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten (May 2011) conducted by Office of Food Safety Center of Food Safety and Applied Nutrition Food and Drug Administration showed that adverse changes in intestinal morphology were detected with exposure to 0.4mg/day. Clinical patient specific symptoms were observed with exposure to 0.015mg. Morphological changes are associated with complications such as lymphoma and gastric carcinoma. Clinical symptoms are varied but include intestinal symptoms such as severe stomach pain, nausea and diarrhea. Extra-intestinal symptoms are varied and include dermatologic (rash), neurologic (headache including migraine, brain fog, learning disability and seizure) and musculoskeletal symptoms such as myalgia and fatigue. Although the hazard study was limited to patients with celiac disease, up to 6% of the population may suffer from non-celiac gluten sensitivity (NCGS) resulting in varying degrees of clinical illness as a result of exposure.

As a result of the existing evidence, FDA established guidelines for the voluntary labeling of food products as “gluten free”, the threshold of 20ppm was established as the standardized criteria for this designation. Although
some patients experience clinical symptoms below this threshold, this served as a guide to patients that labeled
products are produced with an effort to minimize contamination and are tested for gluten content when the risk
exists. It is important to recognize that patients who experience symptoms when consuming a food can make the
choice to no longer purchase and consume the offending product. A medication needs to be taken on schedule
for the prescribed course. Sometimes this schedule involves up to 4 or more dosage units every day.
Currently, insurance does not cover the filling of more than one prescription in a specific period, all but
eliminating the option to try a product from a different manufacturer. Insurance coverage may require
prohibitive copays for the branded drug or more expensive generic products that may not produce the
symptoms. In many cases the only option is to consider the medication a failure, and obtain a prescription for a
different treatment.

Currently, the only known treatment for celiac disease is strict adherence to a gluten free diet. A
prescription requiring “Gluten Free” product is meaningless if products have not been proven and labeled to be
gluten free.

Few products are formulated with gluten containing ingredients listed below*. In a January 2018 article
by Shah in the Journal of Pharmaceutical Sciences titled: Making All Medications Gluten Free, replacing all
gluten containing starch derivatives with alternatives is explored as a way of eliminating the risk of gluten
exposure. Current good manufacturing practices (cGMPs) make contamination during manufacturing highly
unlikely. Unfortunately, there is no current requirement that raw materials used as inactive ingredients in
medication manufacturing be tested, and proven free of gluten contamination. Without assuring that the
ingredients themselves are certified to be free of gluten the risk of contamination remains. For this reason,
pharmacists, and sometimes patients, who call a drug manufacturer, are often told that their product “contains
no gluten containing ingredients”. They are unable to state that the finished product is gluten free because
gluten contamination is not included in post-production batch testing. For food, the product must either have no
risk of contamination based on the content and manufacturing process or that batch test results are less than
20ppm in order to be labeled “Gluten Free”.

Labeling of GF for products with gluten content below 20ppm is voluntary in food products (which may be
avoided by choice in highly sensitive patients who experience adverse clinical effects). We believe that
standards stringent enough to eliminate the risk of symptoms for most celiac patients (0.015mg of daily
exposure at standard dosing) should be imposed on all drug products in the interest of patient safety. Any
product that is not certified at this level of purity should be labeled differently than those that can verify purity.
No one should refuse their medications based on fear of undisclosed gluten contamination. In 2014 the
National Foundation for Celiac Awareness conducted a study resulting in a report, “Gluten in Medication:
Qualifying the Extent of Exposure to People with Celiac Disease and Identifying a Hidden and Preventable
Cause of an Adverse Drug Event”. The study collected reports of celiac patients who experienced symptoms
consistent with gluten exposure while taking medications. A number of these medications were tested for
gluten content using the most sensitive tests available. Gluten contamination above the 20ppm threshold for
gluten free food was identified in some of the reported products even though the manufacturers had stated that
they were made without gluten containing ingredients.

As the elimination of even the smallest amount of gluten is the current treatment plan for millions of
Americans, identifying presence or absence of gluten and labeling this on drug products should be a part of drug
safety standards. Products using excipients with any risk of contamination through processing should be
flagged so that the patient along with their pharmacist can determine the risk/benefit of use. Quantitative
assessment of any known gluten content should ALWAYS be available on request in order to help pharmacists
assist with product selection.

Why now?
In December the FDA posted proposed Gluten in Drug Products and Associated Labeling Recommendations
Guidance for Industry-. Comments were received until February 12th, 2018. NJPhA believes that the
APhA should take a stand on labeling of gluten in medications in order to protect patients this year while
FDA is considering options for dealing with the problem. It is essential that pharmacists be educated on
the disease state and demand the information needed to care for these patients.
References:

Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten. Office of Food Safety-Center of Food Safety and Applied Nutrition Food and Drug Administration-May 2011


Gluten in medication: Qualifying the Extent of exposure to people with celiac disease and identifying a hidden and preventable cause of an adverse drug event” by NFCA (Robert Mangione-Chief investigator)


Other information:

*Ingredients which can be derived from a gluten containing grain:

Wheat, barley or rye may be the source of a limited number of excipients. Examining a medication’s inactive ingredient list for a red-flag ingredient is the only way that people following a medically necessary gluten-free diet and their healthcare providers have to assess for gluten in a drug. The following inactive ingredients may be sourced from wheat, barley or rye:

- Wheat
- Modified starch (source not specified)
- Pregelatinized starch (source not specified)
- Pregelatinized modified starch (source not specified)
- Dextrates (source not specified)
- Dextrin (source not specified but usually corn or potato)
- Dextrimaltose (when barley malt is used)
- Caramel coloring (when barley malt is used)
**Historical Timeline of Progress in Gluten Labeling of Medications**

2008-Private citizen submits a petition to the FDA requesting regulation specifying that no medication, either prescription or OTC, contain wheat gluten as an ingredient, and if this is refused that this ingredient be made known.

2011- Federal Register includes discussion of gluten hazard study: “Based on this health hazard assessment, a conservative tolerable daily intake level for gluten in individuals with celiac disease is 0.4 milligrams (mg) gluten per day for adverse morphological effects and 0.015 mg gluten per day for adverse clinical effects”.

2013- FDA enacts regulation governing the voluntary use if the term “gluten free” to specify finished food products that will test at <20ppm of gluten. Manufacturers had until August 2014 to comply.

2014-September- Results of “Gluten in Medication: Qualifying the Extent of Exposure to People with Celiac Disease and Identifying a Hidden and Preventable Cause of an Adverse Drug Event” by NFCA (Robert Mangione-Chief investigator).

2015- May 12, 2015-FDA responds to citizen petition labeling; request denied because: “Based on drugformulation information, we estimate that these ingredients may contribute no more than 0.5 mg gluten to a unit dose of an oral drug product.”

2015-September-Representatives Tim Ryan (OH-13) and Nita Lowey (NY-17) introduce the Gluten in Medicine Identification Act to Congress.

2015-The FDA responds to the citizen petition which is made public by the recipient that guidance for labeling will be forthcoming.


2018-March APhA considers gluten content labeling in the House of Delegates.

**Current APhA Policy & Bylaws:**


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


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

Introduced by: LT William Christopher Charles
(Name)

2/14/2018
(Date)

United States Public Health Service
(Organization)

Subject: Pharmacists Electronic Referral Tracking

Motion: Move to adopt the following policy statements:

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

Background:

In recent years, APhA has adopted several policies acknowledging the positive impact of pharmacist-provided services. Currently, outside of pharmacy academia, the majority of these services are provided to patients within closed systems such as Veterans Affairs and Kaiser Permanente. Common threads within these systems’ electronic health records (EHR) are universal access of information, and ease of patient referrals to pharmacist services. APhA policy advocates for national EHR integration and pharmacists’ access to the same. A piece that is missing in current policy is a statement focused specifically on the enhancement of referrals within such a system.

Several initiatives have been launched in recent years to expand the successes seen in these systems to more patients. Medical Home Models, Value-Based Payment structures, and Performance Networks are examples of these initiatives. APhA policy also addresses pharmacists’ activities within these structures. The purpose of this proposal is to address the aforementioned missing piece, so pharmacists across practice settings have an avenue to effectively and efficiently coordinate with providers. This will allow many more pharmacists to use their training to the fullest for all patients, whether or not the patients receive their care within a closed health system or innovative health care model.

The National Committee on Quality Assurance (NCQA), which certifies Patient Centered Medical Homes (PCMH), publishes standards and guidelines for practices wishing to provide care in this innovative fashion. PCMHs provide many services inhouse, but often need to refer patients out for specialty care. Complete referrals require the transmission of many pieces of information including the reason for referral, the patient’s PMH, HPI, labs, test results, accurate
medication list, current care plan, therapies previously tried, etc. Inaccurate, incomplete, or delayed transfer of information might result in delayed access to care, duplicate testing, polypharmacy, inappropriate medication use, erosion of trust in the medical system, and increased costs. To avoid these pitfalls and to ensure good coordination of care between PCMHs and outside specialists, NCQA has highlighted efficient referral tracking and follow-up as a must-pass element to gain recognition as a PCMH in each update of its standards since 2011.

The University of California San Francisco (UCSF) in conjunction with San Francisco General Hospital (SFGH), San Francisco’s main safety net provider of specialty care, developed a web-based referral system that allows for interactive communication between referring and specialty providers. A survey of users after the first two years of implementation revealed a host of positive results. Highlights include decreased duplication of diagnostic tests, improved instructions and education back to the primary provider, reduced time to specialist appointment from 5-12 months to 1-2 months, prioritization of referrals based on patients’ needs, time saved for most users, and the reduction of unnecessary referrals. While this referral system did not include pharmacists, some organizations have shown success integrating pharmacists’ services into theirs.

Mountain Area Health Education Family Health Center (MAHEC) is one such NCQA certified PCMH that utilizes pharmacists in an embedded Pharmacotherapy Clinic to provide several services. All clinic activities, which include MTM, osteoporosis management, anticoagulation, diabetes, and medication assistance, are initiated by referral. MAHEC patients also benefit from referrals to unaffiliated community pharmacies for immunization services. The Indian Health Service’s (IHS) National Clinical Pharmacy Specialist Committee has applied this concept directly to pharmacists as well. Their recently updated Comprehensive Pharmacy Services Handbook makes documented, trackable, multidirectional referrals part of their standard operating procedure. The IHS referral-consultation process provides a seamless, electronic transfer of complete, relevant information between providers, allowing pharmacists to coordinate and manage disease states such as Hypertension, Hyperlipidemia, Diabetes, Nicotine Dependence, Asthma, Immunizations, COPD, Hypothyroidism, Spirometry, and more.

The APhA Foundation’s Project IMPACT has devoted many resources to developing collaborative practice agreement (CPA) structures that expand the high level of success seen in the previously described systems to patients in communities across the nation. The Diabetes Ten-City Challenge connected pharmacists with 573 patients who achieved statistically significant improvements in their average A1C, LDL, systolic blood pressure, influenza vaccination rate, eye exam rate, and foot exam rate over an average 14.8-month period. Project IMPACT: Diabetes produced similar results for 1,836 patients in 25 communities in 17 states over an average 11-month period. Notably at the end of the project in 2014, 92% of the communities intended to sustain pharmacists’ services beyond the conclusion of the grant.

Personal interviews with one of the participating pharmacists based in an independent community pharmacy revealed challenges that ultimately ended the CPA for that community. CPAs were entered into with two physicians to see 60 patients. The pharmacist was embedded in one office so had easy access to the EHR and the physician partner. Patients from the other practice were seen in the pharmacy. Referrals were hand written on prescription pads, and all information was transmitted by fax, phone, or hand-delivered by the pharmacist to be scanned into the physician’s EHR later. With the slow flow of information, many patients became confused as to which provider to see for their diabetes care – the physician or the pharmacist. The CPA for the embedded practice was able to sustain for nearly an additional 3 years. The CPA with the remote, paper-based referral system ended shortly after the end of the study period. Based on the successes seen in various previous examples, enhanced & simplified referrals and free-flow of electronic health information likely would have enabled the remote CPA to continue and perhaps expand to more patients and practices.

APhA’s 2015 policy on Interoperability of Communications shows APhA’s support for enhancing electronic communication between healthcare providers and pharmacists, and to that end the Pharmacy Health Information Technology Collaborative (PHITC) has been working with stakeholders to include pharmacists in those standards. Unfortunately, according to the PHITC, the digitization of multidirectional referrals between pharmacists and providers not integrated into a closed health system or innovative health care model is not currently being targeted by any entities.

Due to the work of APhA over the past several years, more states and Congress are moving ever closer toward granting provider status to pharmacists. Now is the time for APhA to pointedly advocate for the development of electronic systems that improve all aspects of the referral interface between providers and pharmacists. Easing this critical transaction of information will do much to enhance pharmacists’ ability to implement CPAs for the care of our patients.
References:


Current APhA Policy & Bylaws:

2017 Patient Access to Pharmacist-Prescribed Medications

4. APhA urges prescribing pharmacists to coordinate care with patients’ other health care providers through appropriate documentation, communication, and referral.

2015 Interoperability of Communications Among Health Care Providers to Improve Quality of Patient Care

1. APhA supports the establishment of secure, portable, and interoperable electronic patient health care records.

2. APhA supports the engagement of pharmacists with other stakeholders in the development and implementation of multidirectional electronic communication systems to improve patient safety, enhance quality care, facilitate care transitions, increase efficiency, and reduce waste.

3. APhA advocates for the inclusion of pharmacists in the establishment and enhancement of electronic health care information technologies and systems that must be interoperable, HIPAA compliant, integrated with claims processing, updated in a timely fashion, allow for data analysis, and do not place disproportionate financial burden on any one health care provider or stakeholder.

4. APhA advocates for pharmacists and other health care providers to have access to view, download and transmit electronic health records. Information shared among providers using a health information exchange should utilize a standardized secure interface based on recognized international health record standards for the transmission of health information.

5. APhA supports the integration of federal, state, and territory health information exchanges into an accessible, standardized, nationwide system.

6. APhA opposes business practices and policies that obstruct the electronic access and exchange of patient health information because these practices compromise patient safety and the provision of optimal patient care.

7. APhA advocates for the development of systems that facilitate and support electronic communication between pharmacists and prescribers concerning patient adherence, medication discontinuation, and other clinical factors that support quality care transitions.

8. APhA supports the development of education and training programs for pharmacists, student pharmacists, and other health care professionals on the appropriate use of electronic health records to reduce errors and improve the quality and safety of patient care.

9. APhA supports the creation and non-punitive application of a standardized, interoperable system for voluntary reporting of errors associated with the use of electronic health care information technologies and systems to enable aggregation of protected data and develop recommendations for improved quality.
2014 Care Transitions

4. APhA supports the development and utilization of standardized processes that facilitate real-time, bidirectional communication of protected health information during care transitions.

2009 Health Information Technology

1. APhA supports the delivery of informatics education within pharmacy schools and continuing education programs to improve patient care, understand interoperability among systems, understand where to find information, increase productivity, and improve the ability to measure and report the value of pharmacists in the health care system.

2. APhA urges that pharmacists have read/write access to electronic health record data for the purposes of improving patient care and medication use outcomes.

3. APhA encourages inclusion of pharmacists in the definition, development, and implementation of health information technologies for the purpose of improving the quality of patient-centric health care.

4. APhA urges public and private entities to include pharmacist representatives in the creation of standards, the certification of systems, and the integration of medication use systems with health information technology.


2006 Continuity of Care

3. APhA supports patient access to pharmacists with specialized skills and expertise. The patient’s pharmacist should make patient referrals where appropriate.

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

Introduced by: _____LT Kinbo Lee__________________________
(Name)

2/13/2018
(Date)

United States Public Health Service
(Organization)

Subject: Pharmacist's Role in Chronic Disease Prevention

Motion: Move to adopt the following policy statements:

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

Background:

A cursory search for “prevention” in the APhA Policy Manual leads to results such as “Poison Prevention,” “Opioid Abuse Prevention,” and preventing the spread of human immunodeficiency virus (HIV) and other sexually-transmitted diseases. However, when it comes to chronic diseases, in general, the profession has largely remained passive in its engagement of primary prevention programs.

According to the CDC\(^1\), in 2015, an estimated 30.3 million people (9.4% of the U.S. population) had diabetes and more than a third of U.S. adults had prediabetes. Despite current diabetes prevention efforts, an estimated 5,200 adults aged 20 years and older are newly diagnosed with diabetes each day\(^2\). In 2015, diabetes was the seventh leading cause of death in the U.S., which cost the U.S. an estimated $245 billion in 2012. Possible complications from diabetes include cardiovascular disease, lower-limb amputation, vision loss, kidney failure, and peripheral neuropathy\(^3\). One of the primary contributors to prediabetes and diabetes is obesity through decreased insulin sensitivity. More than 70% of adults in the U.S. are considered overweight\(^4\). Moreover, over one-third of adults, 20% of adolescents, and 17% of grade-school youth in the U.S. are categorized as obese\(^4,5\). It is estimated that the medical care costs of obesity alone totaled $147 billion in 2008 dollars. Being obese has been found to increase the risk of heart disease, stroke, high blood
pressure, and cancer. Given the health and societal burden of diabetes and obesity on society, individualized lifestyle interventions are paramount to decreasing the incidence of obesity and preventing or delaying onset of diabetes and related complications.

Pharmacists have demonstrated improved health outcomes in patient care through increased medication adherence, patient education, and lifestyle interventions that address modifiable disease risk factors. Specifically, evidence has shown that when pharmacists are involved in management of diabetes and obesity, hemoglobin A1C (HbA1C) and Body Mass Index (BMI) significantly decrease. Meta-analyses of pharmacist interventions to improve diabetic and obesity outcomes report significant A1C reduction (-0.18% to -2.1%) and lowering of BMI (-0.19 kg/m² to -0.9 kg/m²). This is notable given that a 5% reduction in weight loss is associated with lower blood pressure, blood sugar, cholesterol, and insulin resistance, and follows the American Diabetes Association’s recommendation of weight loss for all overweight or obese individuals who have or are at risk for diabetes. In addition, results from Project IMPACT: Diabetes, a program that spanned 25 communities in 17 states, over two years, showed that patients with diabetes who received pharmacist care via customized diabetes education and medication consultation had a statistically significant decrease in mean A1C levels (-0.8%). However, given the large adult population with prediabetes in the U.S. and that 90% of these individuals are unaware of their condition, additional emphasis is needed on diabetes and obesity preventative strategies. In a meta-analysis comparing standard of care in patients with type 2 diabetes to patients with treatment methods that specifically included lifestyle or educational interventions relating to dietary behavior, exercise, or physical activities, A1C (-0.32%, p=0.001) and BMI (-1.05 kg/m², p=0.014) significantly decreased in the intervention group, respectively. In addition, overweight or obese individuals as a cohort who received intensive diet, exercise, and behavioral modification lifestyle modifications in the Diabetes Prevention Program (DPP) had a 58% reduction of risk for diabetes compared to a 31% risk reduction with metformin. Those that received intensive lifestyle modifications in the DPP had a per capita medical costs savings of $4,572 compared to metformin ($2,281) over a 10-year period. Further, it has been shown that pharmacist-led weight loss programs for individuals who are overweight or obese can lead to significant weight reduction (5kg, p<0.001). This gives rise to the importance of pharmacist-provided healthy diet, physical activity, and self-management skill support during patient encounters. Given pharmacists are arguably the most accessible healthcare providers (43% of 312,500 pharmacists work in the community setting), greater than 93% of Americans live within 5 miles of a pharmacy, it seems sensible to further engage pharmacists in preventative patient lifestyle interventions - nutrition intake, physical activity, and weight control - to turn the tide on the diabetes and obesity epidemic.

In November 2017, the Centers for Disease Control and Prevention (CDC) announced a 5-year partnership with the APhA Foundation to implement Project IMPACT: Diabetes Prevention. The program will “build infrastructure within community pharmacies to expand access to innovative evidence-based lifestyle change program designed to prevent or delay the onset of type 2 diabetes among adults with prediabetes” to be delivered through pharmacists, dieticians, and technicians. It will scale up the existing National Diabetes Prevention Program to cover underserved areas through pharmacies. In addition, the CDC will release a new action guide for pharmacists wanting to get involved in the National Diabetes Prevention Program titled “Rx for the National Diabetes Prevention Program: An Action Guide for the Community Pharmacy Workforce.” Furthermore, the Centers for Medicare and Medicaid Services (CMS) issued a second final rule to implement the Medicare Diabetes Prevention Program (MDPP) that opens reimbursement for pharmacists that coordinate a CDC-approved curriculum. This effort complements campaigns from other healthcare professional organizations to prevent or delay type 2 diabetes such as Prevent Diabetes STAT: Screen, Test, Act Today, which is a 2015 partnership between the American Medical Association and the CDC. Through this national effort, pharmacists can now be recognized for their integral role in advancing and promoting public health.
References

Current APhA Policy & Bylaws:

2013 Pharmacists Providing Primary Care Services

1. APhA advocates for the recognition and utilization of pharmacists as providers to address gaps in primary care.

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

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)

2012, 1981 Pharmacist Training in Nutrition

1. APhA advocates that all pharmacists become knowledgeable about the subject of nutrition.
2. APhA encourages schools and colleges of pharmacy as well as providers of continuing pharmacy education to offer education and training on the subject of nutrition.


2012, 2005, 1992 The Role of Pharmacists in Public Health Awareness

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.


2012 Contemporary Pharmacy Practice

1. APhA asserts that pharmacists should have the authority and support to practice to the full extent of their education, training, and experience in delivering patient care in all practice settings and activities.
2. APhA supports continuing efforts that lead to the establishment of a consistent and accurate perception by the public, lawmakers, regulators, and other health care professionals of the role and contemporary practice of pharmacists.
3. APhA supports continued collaboration with stakeholders to facilitate adoption of standardized practice acts, appropriate related laws, and regulations that reflect contemporary pharmacy practice.
4. APhA supports the establishment of multistate pharmacist licensure agreements to address the evolving needs of the pharmacy profession and pharmacist-provided patient care.

5. APhA urges the development of consensus documents, in collaboration with medical associations and other stakeholders, that recognize and support pharmacists’ roles in patient care as health care providers.

6. APhA urges universal recognition of pharmacists as health care providers and compensation based on the level of patient care provided using standardized and future health care payment models.

JPhA NS52(4) 457 July/August 2012 (Reviewed 2016)

2011 The Role and Contributions of the Pharmacist in Public Health

1. 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.

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

2004, 1978 Roles in Health Care for Pharmacist

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.


**Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

New Business Items are due to the Speaker of the House by **February 14, 2018** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.