

Expanding Opportunities
through Patient Care



Annual Meeting & Exposition
Baltimore, MD March 4-7



APhA HOUSE OF DELEGATES

DELEGATE REFERENCE MATERIALS

March 4-7, 2016
Baltimore, MD





MEMORANDUM

TO: Delegates and Alternate Delegates to the APhA House of Delegates
FROM: Theresa Tolle, 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 Baltimore, 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;
- 2015-2016 APhA House Rules Review Report;
- 2015-2016 APhA Policy Review Committee Report;
- 2015-2016 APhA Policy Committee Report; and
- 2015-2016 APhA New Business Items received

Policy-Related Webinars Available

If you were unable to participate in one of these offerings, I encourage you to visit <http://pharmacist.com/learn-about-0> to view an archived version of the *Open Forum on 2016 Proposed Policy Statements*. This webinar will give you additional background information on the policy topics, provide the context of the Policy Committee's discussions, and answer 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 17, 2016 and from 7:00-8:30pm on February 24, please try to participate in one of the two webinars. These webinars will provide an opportunity for you to learn more about the items submitted prior to the Annual Meeting and gives you adequate time to prepare for House discussions. You must register to participate in the webinars. If you find that you are unable to participate in one of the live webinars, an archived version will be available online soon after.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 want a refresher course on the rules and procedures of the APhA House, I encourage you to view the ***Delegate Orientation Webinar recording available online***.

Delegate Registration

Onsite Delegate registration for the First Session will be open from **12:00pm-3:30pm on Friday, March 4, 2016, outside of Room 310 of the Convention Center**. Registration for the Final will be open in the same location, from **11:00am-2:00pm on Monday, March 7, 2016**. Unless you would like to pick up your Delegate ribbon in advance, there is no need to check-in with the House of Delegates Office or with APhA staff 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 **Room 310**. Please remember to bring your delegate reference materials and your name badge with you to registration.
- 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.

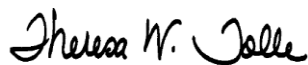
Planning for the 2017 House

It's never too early to plan ahead! In early April, APhA will begin the policy development process for 2017. 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 Baltimore, or submit the form electronically by **March 23, 2016** at <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 2016-2017 policy development process, I encourage you to complete the committee volunteer interest form **by June 15, 2016** at <http://fs3.formsite.com/apha/form217/index.html>.

Thank you again for your interest and service to the 2016 House of Delegates! I look forward to seeing you in Baltimore! If you have any questions about House activities, please visit <http://www.pharmacist.com/apha-house-delegates> or contact APhA staff at hod@aphanet.org.

Sincerely,



Theresa Tolle, BPharm
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, Senior Manager, Governance
Wendy Gaitwood, Senior Administrative Manager, Policy & Governance

Online: <http://www.pharmacist.com/apha-house-delegates>

Email: hod@aphanet.org

Delegates Checklist

Prior to the Meeting:

- ☐ Sign-up for the House sessions you wish to attend [here](#)
- ☐ Review 2016 posted [House webinars](#)
- ☐ Join in policy discussions via [APhA Engage](#) HOD communities
- ☐ Review Delegate Materials prior to the HOD meeting
- ☐ Prepare your amendment recommendations prior to House proceedings ([Sample Amendment forms](#))

While at the Meeting: (Check the Schedule At A Glance for Time/Room Information)

- ☐ Delegate Check-in outside of Room 310 on Friday, March 4 between 12:00 pm – 3:30 pm to receive your Delegate ribbon and voting device (Must be seated by 2:45 pm)
- ☐ Saturday, March 5 - New Business Review Committee Open Hearing -
- ☐ Sunday, March 6 - Policy Committee Open Hearing
- ☐ Delegate Check-in outside of Room 310 on Monday, March 7 between 11:00 am - 2:00 pm to receive your Delegate ribbon and voting device (Must be seated by 1:15 pm)

After the Meeting:

- ☐ Submit 2017 Policy Topic Ideas online by **March 23, 2016** at <http://fs3.formsite.com/apha/form220/index.html>
- ☐ Volunteer to sit on a 2017 House Committee before **June 15, 2016** at <https://fs3.formsite.com/apha/form217/index.html>
- ☐ Contact your State, Academy or Recognized Organization to make sure you are listed as a delegate for 2016-2017!

APhA House of Delegates Online: <http://www.pharmacist.com/apha-house-delegates>

APhA Email: hod@aphanet.org



APhA-ASP (Delegates-28)

Afeefa Bhatti
Alyssa Billmeyer
Lauren Bode
Nicole Clay
Jessica Comstock
Joseph ElAshkar
Kaity Erickson
Jared Frye
Tingting Fu
Jason Gaines
Kelsea Gallegos
Stephanie Garza
Eileen Hang
Adam Heiermann
Nimit Jindal
Jennifer Levine
Kevin Mai
Benjamin Morris
Edwin Murphy
Saranpreet Nagra
Lauren San Juan
Allie Shipman
Bethany Sibbitt
Anne Stella
Jeffrey Van Liew
Samantha Westmoreland
Alexandria Ybarra
Jing Zhu

APhA-ASP (Alt. Delegates)

Rachel Brunner
Laura Byrd
Amanda Cavness
Ifeoma Ibe
Morgan Land
Stacy Longo
Wilhelmina Lord-Adem
Juliet Nguyen
Shiny Parsai
Ann Tabutsadze
Katrina Watson
Claire Weidman

APhA-APPM (Delegates-28)

Dusty Allen
Chelsea Anderson
Amber Beals
Jeffrey Bratberg
Amber Briggs
Andrew Bzowickyj
Denise Clayton
Robin Cooke
Melissa Duke
Brian Fingerson
Heather Free
Nicole Gattas
Brigid (Long) Groves
Nicki Hilliard
Amy Kennedy
James Kirby
Catherine Kuhn
Phillip Lawrence
Monali Majmudar
Bella Mehta
Wendy Mobley-Bukstein
Cortney Mospan
Sarah Ray
Blair Sarbacker
Michael Schuh
Sheila Seed
Larry Selkow
Daniel Zlott

APhA-APPM (Alt. Delegates)

Ron Debellis
Abimbola Farinde
Jeffrey Hamper
Theresa Ofili
Martha Rumore
Frances Thexton

APhA-APRS (Delegates-28)

Jill Augustine
Edward Bednarczyk
Gregory Calip
Anthony Di Pasqua
Robert DiCenzo
Joseph Dikun
Joel Farley
Patricia Freeman
Ronald Hadsall

Brandi Hamilton
Adriane Irwin
Eric Jarvi
Patricia Lind
Eric Mack
Joey Mattingly
Bill McLaughlin
Amanda Meeker
Karen Nagel-Edwards
Julie Oestreich
Anthony Palmieri
Mary Piascik
Brent Reed
Andrew Roberts
Kimberly Scarsi
Zia Shariat-Madar
Terri Warholak

APhA-APRS (Alt. Delegates)

Darius Mason
Gary Smith

BOARD OF TRUSTEES (15)

Nancy Alvarez
Tery Baskin
Lawrence Brown
Gregory Fox
Jean-Venable Goode
Dennis Helling
Linda MacLean
Thomas Menighan
Matthew Osterhaus
Melody Ryan
Ronald Small
Bradley Tice
Wendy Weber
Theresa Wells-Tolle
Lucianne West

AIR FORCE (Delegates-2)

Richard Caballero
Rodney Jorstad

AIR FORCE (Alt. Delegates)

Krissa Crawford
Bernard VanPelt

ARMY (Delegates-2)

Kevin Ridderhoff

NAVY (Delegates-2)

Heather Hellwig
Tiffany Scott

NAVY (Alt. Delegates)

Benedict Baidoo
David Vera

PUBLIC HEALTH SERV. (Delegates-2)

Irene Ahlstrom
Amy Luo

PUBLIC HEALTH SERV. (Alt. Delegates)

Patrick Harper
Garrette Martin-Yeboah

VETERANS ADMIN. (Delegates)-2)

Mariano Franchi
Ronald Nosek

VETERANS ADMIN. (Alt. Delegates)

Jeanne Tuttle
Jennifer Zacher

APhA-FORMER PRESIDENTS (32)

Lowell Anderson
William Appel
Maurice Bectel
Marialice Bennett
J Bootman
Grover Bowles
Bruce Canaday
R David Cobb
Robert Davis
George Denmark
James Doluisio
Janet Engle
Philip Gerbino
Robert Gibson
Harold Godwin
Charles Green
Ed Hamilton
Ronald Jordan
Gary Kadlec
Calvin Knowlton
Winnie Landis
Eugene Lutz
James Main
Jacob Miller
Robert Osterhaus

Marily Rhudy
Steven Simenson
Jenelle Sobotka
Kenneth Tiemann
Lisa Tonrey
Timothy Tucker
Timothy Vordenbaumen
William Whitten

APhA-FORMER SPEAKERS (18)

Susan Bartlemay
Bethany Boyd
Leonard Camp
Betty Jean Harris
Lucinda Maine
Michael Mone
Craig Pedersen
Adele Pietrantoni
Hazel Pipkin
Valerie Prince
William Riffie
Michael Smith
Elizabeth Valentine
Pamela Whitmire
Wilma Wong

AMCP (Delegates-2)

Susan Cantrell
Ashley Lanham

AACP (Delegates-2)

Cynthia Boyle
Joseph DiPiro

AACP (Alt. Delegate)

Lynette Bradley-Baker

ACCP (Delegates-2)

Terry Seaton
C Edwin Webb

ACCP (Alt. Delegates)

Daniel Aistrope
Michael Maddux

AIHP (Delegates-2)

Gregory Higby
William Zellmer

ASPL (Delegates-2)

Laura Carpenter
Steven Gray

ASCP (Delegates-2)

Sharon Clackum

ASHP (Delegates-2)

Christene Jolowsky
Kasey Thompson

IACP (Delegates-2)

Erik Tosh
John Voliva

NCPA (Delegates-2)

John Beckner
Robert Greenwood

NPhA (Delegates-2)

Erica Hanesworth
Joseph Lee

NRPhA (Delegates-2)

Thomas Hanson
Moir Maroney

SPEAKER APPOINTED (10)

Sarah Barden
Megan Carroll
Rebecca Chater
Matthew Lacroix
David Steeb
Brenna Lindsey-Swecker
Benjamin Urick
Veronica Vernon
Krystalyn Weaver

ALABAMA (Delegates-4)

Byrdena Dugan
Michael Hogue
Rebecca Sorrell
Charles Thomas

ALABAMA (Alt. Delegate)

Ralph Sorrell

ALASKA (Delegates-2)

Tara Ruffner
Laura Vaughn

ALASKA (Alt. Delegate)

Adele Garrison

*The numbers reflect the allotted delegates per delegation, not the actual listed delegates.

ARIZONA (Delegates-5)

Mark Boesen
Pamela Piotrowski
Whitney Rice

ARIZONA (Alt. Delegate)

Kelly Fine – State Exec.

ARKANSAS (Delegates-4)

Kevin Barton
Brenna Button-Neumann
Schwanda Flowers
Jeanie Monzingo Smith

ARKANSAS (Alt. Delegate)

Eric Crumbaugh

CALIFORNIA (Delegates-11)

Kathleen Besinque
Sonya Frausto
Karl Hess
Douglas Hillblom
Ethan Huynh
Elizabeth Johnson
Sarah McBane
Edlen Wong
Chris Woo
George Yasutake

CALIFORNIA (Alt. Delegates)

Tony Park
Daniel Robinson

COLORADO (Delegates-3)

Jeannine Dickerhofe
Randy Knutsen
Ann McManis

COLORADO (Alt. Delegate)

Samuel Johnson

CONNECTICUT (Delegates-3)

Valentino Caruso
Meghan Wilkosz

CONNECTICUT (Alt. Delegate)

Margherita Giuliano – State Exec.

DELAWARE (Delegates-2)

Kevin Musto
Kimberly Robbins

DISTRICT OF COLUMBIA (Delegates-2)

Tamara McCants
Carolyn Rachel-Price

DISTRICT OF COLUMBIA (Alt. Delegate)

Terri Moore – State Exec.

FLORIDA (Delegates-7)

Natalie Ciccone
Jackie Donovan
William Garst
Katherine Petsos
Norman Tomaka
Scott Tomerlin
Karen Whalen

FLORIDA (Alt. Delegate)

Michael Jackson – State Exec.

GEORGIA (Delegates-5)

Lance Boles
Liza Chapman
James England
Pamala Marquess
Thomas Whitworth

GEORGIA (Alt. Delegate)

Mary Meredith

GUAM (Delegates-2)**HAWAII (Delegate-2)**

Ronald Taniguchi

DAHO (Delegate-2)

Donald Smith

ILLINOIS (Delegates-7)

Lauren Angelo
Ed Cohen
Starlin Haydon-Greatting
Jessica Kerr
Laura Licari
Garth Reynolds – State Exec.
Cynthia Russell

ILLINOIS (Alt. Delegate)

Judith Sommers Hanson

INDIANA (Delegates-4)

Stephanie Arnett
Jackie Bowen
Lynn Fletcher
Tamara Fox

IOWA (Delegates-4)

Steve Firman
Rick Knudson
John Swegle
Coralynn Trewet

IOWA (Alt. Delegates)

Anthony Pudlo
Kate Gainer – State Exec.

KANSAS (Delegates-4)

Carl Benton
Robert Emerson
Emily Prohaska

KANSAS (Alt. Delegate)

Mike Larkin – State Exec.

KENTUCKY (Delegates-4)

Chris Clifton
Kimberly Croley
Suzanne Francis
Amanda Jett

KENTUCKY (Alt. Delegates)

Robert McFalls – State Exec.

LOUISIANA (Delegates-4)

Aurdie Bellard
Lisa Bertucci
Robert Toups
Anthony Walker

MAINE (Delegates-2)

Stephanie Lewis
Deborah Sturpe

MAINE (Alt. Delegate)

Kenneth McCall – State Exec.

MARYLAND (Delegates-5)

James Dvorsky
DeAnna Leikach
Ashley Moody
Matthew Shimoda
Hoai An Truong

*The numbers reflect the allotted delegates per delegation, not the actual listed delegates.

MARYLAND *(Alt. Delegates)*

G Hogue
Aliyah Horton – State Exec.

MASSACHUSETTS *(Delegates-5)*

Susan Holden
Karen Poliskey
Nirali Rana

MICHIGAN *(Delegates-6)*

Mark Bomia
Kimberly Proffer
Frederick Schmidt
Amy Smendik
Larry Wagenknecht – State Exec.
Andrew Young

MICHIGAN *(Alt. Delegate)*

Dianne Malburg

MINNESOTA *(Delegates-5)*

Kati Dvorak
Lara Kerwin
Kieu Le
Anthony Olson
Scott Setzepfandt

MISSISSIPPI *(Delegates-2)*

David Allen
Jillian Foster

MISSISSIPPI *(Alt. Delegate)*

Olivia Strain

MISSOURI *(Delegates-5)*

Russell Melchert
John Pieper
Elizabeth Rodman

MONTANA *(Delegates-2)*

Marcie Bough
Lyndee Fogel

NEBRASKA *(Delegates-3)*

Allison Dering-Anderson
Edward DeSimone
Allison Strobel

NEBRASKA *(Alt. Delegate)*

Jennifer Tilleman

NEVADA *(Delegates-3)*

Mark Decerbo
Christina Quimby
Eric Shalita

NEW HAMPSHIRE *(Delegates-2)*

Cheryl Abel
Cheryl Durand

NEW HAMPSHIRE *(Alt. Delegate)*

Megan Januszewski

NEW JERSEY *(Delegates-6)*

Elise Barry – State Exec.
Ruth Marietta
James Moore
Sandra Moore
Lucio Volino
Steven Zlotnick

NEW MEXICO *(Delegates-2)*

Michel Disco
Lynda Welage

NEW YORK *(Delegates-8)*

NORTH CAROLINA *(Delegates-5)*

Ashley Branham
Fred Eckel – State Exec.
Stephen Eckel
Macary Marciniak

NORTH DAKOTA *(Delegates-2)*

Michael Schwab – State Exec.
Wanda Roden

OHIO *(Delegates-8)*

Kelli Barnes
Kimberly Broedel-Zaugg
Andrew Faiella
Cari Fink
Thad Franz
Matthew Lengel
Erin Petersen
Alexa Sevin

OHIO *(Alt. Delegates-2)*

Craig Kimble
Nicholas Newman

OKLAHOMA *(Delegate-2)*

OKLAHOMA *(Alt. Delegate)*

Debra Billingsley – State Exec.

OREGON *(Delegates-3)*

Jill McClellan
Marc Rizzo
Kevin Russell

OREGON *(Alt. Delegate)*

Irene Crosswell

PENNSYLVANIA *(Delegates-9)*

Mayank Amin
Brandon Antinopoulos
Richard Demers
Julie Gerhart
Daniel Hussar
Mary McManus
Julie Olenak
Roshni Patel
Eric Pusey

PENNSYLVANIA *(Alt. Delegates)*

Kimberly Carter
Kristal Ross

PUERTO RICO *(Delegates-2)*

Nelson Cordero Gonzalez
Milagros Morales

RHODE ISLAND *(Delegates-2)*

Daniel Lefkowitz
Lynn Pezzullo

SOUTH CAROLINA *(Delegates-4)*

Kayce Shealy
George Vess
William Wynn

SOUTH CAROLINA *(Alt. Delegate)*

Linda Reid

SOUTH DAKOTA *(Delegate-2)*

Melanie Sommers

TENNESSEE *(Delegates-6)*

Lucy Adkins
McKenzie Calhoun
Micah Cost – State Exec.
Cindy Fisher
Loren Kirk
Leslie Shepard

*The numbers reflect the allotted delegates per delegation, not the actual listed delegates.

TEXAS *(Delegates-8)*

Laura Beall
M. Lynn Crismon
Shara Elrod
Carole Hardin-Oliver
Mary Klein
Carol Reagan
Douglas Ried
May Woo

UTAH *(Delegates-3)*

Kyle Kitchen
Jonathan Magness
Buck Stanford

VERMONT *(Delegates-2)*

VIRGINIA *(Delegates-6)*

Thomas Fagan
Colleen Harmon
Leslie Hausser
Michelle Herbert Thomas
William Lee
Dominic Solimando

VIRGINIA *(Alt. Delegates)*

Margaret Robinson
Timothy Musselman – State Exec.

WASHINGTON *(Delegates-4)*

Leon Alzola
Collin Conway
Sara McElroy
Donald Williams

WASHINGTON *(Alt. Delegates)*

Jeffrey Rochon – State Exec.

WEST VIRGINIA *(Delegates-3)*

Krista Capehart
Betsy Elswick
Karen Reed

WEST VIRGINIA *(Alt. Delegate)*

Gretchen Garofoli

WISCONSIN *(Delegates-3)*

Anthony Ball
Nicholas Capote
Audrey Kostrzewa

WYOMING *(Delegates-2)*

*The numbers reflect the allotted delegates per delegation, not the actual listed delegates.

American Pharmacists Association House of Delegates

FIRST SESSION

Friday, March 4, 2016

3:00PM – 5:00PM

SEATING CHART

Speaker of the House

1	AL-4	AR-4		20	MD-5+	MS-2		39	(S)	OR-3
2	AK-2	AZ-5	(S)	21	MA-5	MT-2		40	RI-2	PA-2
3	CA-8			22	MI-6*	ND-2		41	PA-4	
4	CA-3	CO-3	DC-2	23	(S) MN-5	NH-2		42	(S)	PA-3
5	DE-2	IN-4	(F)	24	NC-5*	NV-3		43	PR-2	TN-2
6	FL-7+			25	NY-8			44	TN-4	
7	GA-5	HI-2	(S)	26	(F)	NJ-6*	(S)	45	TX-8	
8	CT-3	IA-4+		27	MO-5	OK-2+		46	(F) SD-2	UT-3 VT-2
9	IL-7+			28	OH-8			47	(S)	VA-6+
10	KY-4+	NE-3		29	ME-2+	SC-4	(S)	48	WA-4+	WV-3
11	ID-2	KS-4+	(S)	30	ASHP, IACP, NPhA, NRPhA			49	(F) WY-2	WI-5
12	LA-4	GU-2	NM-2	31	AAPS, AIHP, AMCP, ASCP			50	NCPA, Air Force, Army, Navy	
13	AACP, ACCP, ACA, ASPL			32	(F)	Speaker Appointed-6	(F)	51	Speaker Appt., PHS, Vet Admin.	
14	APhA-APRS-7			33	APhA-ASP-7			52	(S)	APhA-APPM-7
15	APhA-APRS-7			34	(S)	APhA-ASP-7		53	APhA-APPM-7	
16	APhA-APRS-7		(S)	35	APhA-ASP-7			54	APhA-APPM-7	
17	APhA-APRS-7			36	(S)	APhA-ASP-7		55	APhA-APPM-7	
18	Former Presidents-6			37	Former Speakers-8			56	(S)	Board of Trustees-7
19	Former Presidents-8			38	Former Speakers-8			57	Board of Trustees-8	

KEY

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

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

(F) = Former Speaker

(S) = APhA Staff Member

American Pharmacists Association House of Delegates

FIRST SESSION

Friday, March 4, 2016

3:00PM – 5:00PM

SEATING CHART BY DELEGATION NAME

Alabama – Table 1
Alaska – Table 2
Arizona – Table 2
Arkansas – Table 1
California – Tables 3 & 4
Colorado – Table 4
Connecticut – Table 8
Delaware – Table 5
District of Columbia – Table 4
Florida – Table 6
Georgia – Table 7
Guam – Table 12
Hawaii – Table 7
Idaho – Table 11
Illinois – Table 9
Indiana – Table 5
Iowa – Table 8
Kansas – Table 11
Kentucky – Table 10
Louisiana – Table 12
Maine – Table 29
Maryland – Table 20
Massachusetts – Table 21
Michigan – Table 22
Minnesota – Table 23
Mississippi – Table 20
Missouri – Table 27

Montana – Table 21
Nebraska – Table 10
Nevada – Table 24
New Hampshire – Table 23
New Jersey – Table 26
New Mexico – Table 12
New York – Table 25
North Carolina – Table 24
North Dakota – Table 22
Ohio – Table 28
Oklahoma – Table 27
Oregon – Table 39
Pennsylvania – Tables 40, 41 & 42
Puerto Rico – Tables 43
Rhode Island – Table 40
South Carolina – Table 29
South Dakota – Table 46
Tennessee – Table 43 & 44
Texas – Table 45
Utah – Table 46
Vermont – Table 46
Virginia – Table 47
Washington – Table 48
West Virginia – Table 48
Wisconsin – Table 49
Wyoming – Table 49

AAPS – Table 31
AACP – Table 13
ACA – Table 13
ACCP – Table 13
AIHP – Table 31
AMCP – Table 31
ASHP – Table 30
ASCP – Table 31
ASPL – Table 13
NCPA – Table 50
IACP – Table 30
National Pharmaceutical Assn. – Table 30
National Pharmacists Assn. – Table 30
Air Force – Table 50
Army – Table 50
Navy – Table 50
Public Health Service – Table 51
Veterans Administration – Table 51
APhA-APPM – Tables 52, 53, 54 & 55
APhA-APRS – Tables 14, 15, 16 & 17
APhA-ASP – Tables 33, 34, 35 & 36
Speaker-Appointed Delegates – Tables 32 & 51
APhA Board of Trustees – Tables 56 & 57
APhA Former Presidents – Tables 37 & 38
APhA Former Speakers – Tables 18 & 19

American Pharmacists Association House of Delegates

FINAL SESSION

Monday, March 7, 2016

1:30PM – 4:30PM

SEATING CHART

Speaker of the House

1	LA-4	GU-2	NM-2	20	(S)	ME-2+	SC-4	39	TX-4
2	ID-2	KS-4+	(S)	21		OH-8		40	TX-4
3	KY-4+	NE-3		22		MO-5	OK-2+	41	(S) UT-3
4	IL-7+			23	(F)	NJ-6*		42	VA-3+
5	CT-3	IA-4+		24		NY-8		43	(S) VA-3
6	GA-5	HI-2	(S)	25		NC-5*	NV-3	44	RI-2 SD-2
7	FL-7+			26		MN-5	NH-2 (S)	45	(F) VT-2 WI-5
8	DE-2	IN-4	(F)	27		MI-6*	ND-2	46	WY-2 WV-3 PA-3
9	CA-3	CO-3	DC-2	28	(S)	MA-5	MT-2	47	PA-6 PR-2
10	CA-8			29		MD-5+	MS-2	48	OR-3 WA-4+
11	AK-2	AZ-5	(S)	30		ASHP, IACP, NPhA, NRPhA		49	(F) (S) TN-6
12	AL-4	AR-4		31		AAPS, AIHP, AMCP, ASCP		50	NCPA, Air Force, Army, Navy
13	AACP, ACCP, ACA, ASPL			32	(F)	Speaker Appointed-6	(F)	51	(S) Speaker Appt., PHS, Vet Admin.
14	APhA-APRS-7			33	(S)	APhA-ASP-7		52	APhA-APPM-7
15	APhA-APRS-7	(S)		34		APhA-ASP-7		53	APhA-APPM-7
16	APhA-APRS-7			35		APhA-ASP-7		54	APhA-APPM-7
17	APhA-APRS-7	(S)		36	(S)	APhA-ASP-7		55	APhA-APPM-7
18	Former Presidents-6			37		Former Speakers-8		56	(S) Board of Trustees-7
19	Former Presidents-8			38		Former Speakers-8		57	Board of Trustees-8

KEY

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

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

(F) = Former Speaker

(S) = APhA Staff Member

American Pharmacists Association House of Delegates
FINAL SESSION
Monday, March 7, 2016
1:30PM – 4:30PM

SEATING CHART BY DELEGATION NAME

Alabama – Table 12
Alaska – Table 11
Arizona – Table 11
Arkansas – Table 12
California – Tables 9 & 10
Colorado – Table 9
Connecticut – Table 5
Delaware – Table 8
District of Columbia – Table 9
Florida – Table 7
Georgia – Table 6
Guam – Table 1
Hawaii – Table 6
Idaho – Table 2
Illinois – Table 4
Indiana – Table 8
Iowa – Table 5
Kansas – Table 2
Kentucky – Table 3
Louisiana – Table 1
Maine – Table 20
Maryland – Table 29
Massachusetts – Table 28
Michigan – Table 27
Minnesota – Table 26
Mississippi – Table 29
Missouri – Table 22

Montana – Table 28
Nebraska – Table 3
Nevada – Table 25
New Hampshire – Table 26
New Jersey – Table 23
New Mexico – Table 1
New York – Table 24
North Carolina – Table 25
North Dakota – Table 27
Ohio – Table 21
Oklahoma – Table 22
Oregon – Table 48
Pennsylvania – Tables 46 & 47
Puerto Rico – Tables 47
Rhode Island – Table 44
South Carolina – Table 20
South Dakota – Table 44
Tennessee – Table 49
Texas – Table 39 & 40
Utah – Table 41
Vermont – Table 45
Virginia – Table 42 & 43
Washington – Table 48
West Virginia – Table 46
Wisconsin – Table 45
Wyoming – Table 46

AAPS – Table 31
AACP – Table 13
ACA – Table 13
ACCP – Table 13
AIHP – Table 31
AMCP – Table 31
ASHP – Table 30
ASCP – Table 31
ASPL – Table 13
NCPA – Table 50
IACP – Table 30
National Pharmaceutical Assn. – Table 30
National Pharmacists Assn. – Table 30
Air Force – Table 50
Army – Table 50
Navy – Table 50
Public Health Service – Table 51
Veterans Administration – Table 51
APhA-APPM – Tables 52, 53, 54 & 55
APhA-APRS – Tables 14, 15, 16 & 17
APhA-ASP – Tables 33, 34, 35 & 36
Speaker-Appointed Delegates – Tables 32 & 51
APhA Board of Trustees – Tables 56 & 57
APhA Former Presidents – Tables 37 & 38
APhA Former Speakers – Tables 18 & 19

Expanding Opportunities
through Patient Care



Annual Meeting & Exposition
Baltimore, MD March 4-7



House of Delegates Schedule At A Glance

FRIDAY, MARCH 4

12:00 pm – 3:30 pm	Outside Room 310	Delegate Registration
1:00 pm – 2:30 pm	Room 346	APhA-APPM Delegate Caucus
1:00 pm – 2:30 pm	Room 347	APhA-APRS Delegate Caucus
3:00 pm – 5:00 pm	Room 307 – 310	House of Delegates – First Session (Be seated by 2:45pm)

SATURDAY, MARCH 5

1:00 pm – 2:30 pm	Room 343/344	New Business Review Committee Open Hearing
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SUNDAY, MARCH 6

1:00 pm – 3:00 pm	Room 343/344	Policy Committee Open Hearing
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MONDAY, MARCH 7

7:00 am – 9:30 am	Room 347	APhA-APPM Delegate Caucus
9:30 am – 11:00 am	Room 346	APhA-APRS Delegate Caucus
11:00 am – 2:00 pm	Outside Room 310	Delegate Registration
1:30 pm – 4:30 pm	Room 307 – 310	House of Delegates – Final Session (Be seated by 1:15pm)

House of Delegates Office Hours - Room 311

Thursday, March 3	3:00 pm – 6:00 pm
Friday, March 4	7:30 am – 3:00 pm
Saturday, March 5	8:00 am – 3:00 pm
Sunday, March 6	8:00 am – 3:00 pm
Monday, March 7	7:30 am – 1:00 pm

FRIDAY, MARCH 4

House of Delegates – First Session

Agenda

1. Call to Order
2. Review of Voting Procedures
3. Credentials Report*
4. Adoption of Agenda and Rules*
5. Introduction of Head Table
6. Report of the Speaker, APhA House of Delegates
7. APhA House Rules Review Committee Report*
8. New Business Procedure
9. Report of the Committee on Nominations*
10. Speaker-elect Candidate Introduction
11. APhA Policy Review Committee Report – Part 1 (Received)
12. APhA Policy Committee Report (Received)
13. Adjourn to a Committee of the Whole for Discussion of the Policy Review Committee and Policy Committee Reports*
 - a. APhA Policy Review Committee Report
 - b. APhA Policy Committee Report
14. APhA Policy Review Committee Report Considerations*
15. APhA Policy Committee Report Considerations*
16. Recognition of APhA and Academy Officers – 2016 APhA Officers' Report
17. Meet the Candidates for the 2016 APhA Board of Trustees Election
18. Housekeeping Announcements
19. Adjournment of the First House Session

MONDAY, MARCH 7

House of Delegates – Final Session

Agenda

1. Call to Order
2. Review of Voting Procedures
3. Credentials Report*
4. Adoption of Agenda*
5. Consideration of Unfinished Business
 - a. APhA Policy Committee Report*
 - b. APhA Policy Review Committee Report – Part 2*
6. Speaker-elect Candidate Speeches
7. Speaker-elect Election*
8. Consideration of New Business*
9. Announcement of Election Results
10. Installation of the 2016-2017 Speaker-elect
11. Installation of the APhA Board of Trustees
12. Installation of the 2016-2017 APhA President
13. Recommendations from APhA Members
14. Closing Announcements
15. Adjournment of the 2016 APhA House of Delegates

Please note: (*) asterisk indicates potential opportunities to cast votes.



General Information for Delegates

DUTIES OF THE HOUSE OF DELEGATES	<p>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.</p> <p>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.</p>
COMPOSITION OF THE HOUSE OF DELEGATES	<p>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.</p> <p>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.</p> <p>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</p>
CERTIFICATION OF DELEGATES	<p>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. 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.</p>
OFFICERS OF THE HOUSE OF DELEGATES	<p>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.</p>
DELEGATE ORIENTATION	<p>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..</p>

APhA HOUSE RULES REVIEW COMMITTEE	<p>The House Rules Review Committee is charged to review and establish rules and procedures for the conduct of business at each House session.</p> <p>The Committee meets via conference call at least twice a year:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
APhA POLICY COMMITTEE	<p>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.</p> <ul style="list-style-type: none"> • 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	<p>The APhA Policy Reference Committee is charged with providing greater participation in the policy development process and ensuring objective consideration of APhA member comments.</p> <ul style="list-style-type: none"> • 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	<p>The APhA Policy Review Committee is charged to ensure that adopted policy is relevant and reflects the opinion of the contemporary pharmacy community.</p> <ul style="list-style-type: none"> • The Committee meets via conference call to determine whether adopted policy statements should be retained, archived, or rescinded. The Committee can propose New Business Items for those statements needing amendment. • The Committee's review is divided into two parts. <ul style="list-style-type: none"> ○ Part One reviews adopted policy statements according to the schedule outlined in the House of Delegates Rules of Procedure. ○ Part Two 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	<p>The New Business Review Committee is charged to review proposed policy submitted by Delegates and recommend action on those items.</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
SUBMISSION OF NEW BUSINESS ITEMS	<p>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 done with a suspension of House rules at the House Session where New Business will be acted upon.</p>
DISTRIBUTION OF MATERIALS IN THE HOUSE OF DELEGATES	<p>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.</p>
HOUSE OF DELEGATES RULES OF ORDER	<p>The rules contained in <i>Robert's Rules of Order Newly Revised</i> 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.</p>
ACCESS TO THE FLOOR OF THE HOUSE OF DELEGATES	<p>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.</p>
AVAILABILITY OF REPORTS	<p>The final report of the APhA Policy Committee will be available to membership by 8:00AM on Monday in the House of Delegates Office. The final report of the APhA New Business Review Committee will be available by 8:00AM on Sunday in the House of Delegates Office.</p>
VOTING PROCEDURES	<p>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.</p>

American Pharmacists Association

House of Delegates

Rules of Procedure

Updated 2015

The following information reflects the final language adopted by the 2015 APhA House of Delegates.

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 “friendly” amendments. The Speaker will rule any Delegates out of order who express a desire to make a “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, or retain, all such existing policy, with limited debate, shall be in order. Items identified by the Policy Review Committee as needing amendment shall be submitted to the New Business Review Committee for consideration, if the amendment changes the original policy intent. Any such existing policy will be subject to review every five years or less. Starting with the 2014-2015 Policy Review Committee, and every 4 years from there (not on an even year when there is a Speaker election), the Policy Review Committee shall review any policy that has not been reviewed or had policies added in the past 4 years.

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.

Parliamentary Procedures At A Glance

<i>To Do This:</i>	<i>You Say This:</i>	<i>Must you interrupt speaker?</i>	<i>Must you be seconded?</i>	<i>Debatable?</i>	<i>Amendable?</i>	<i>Vote Required</i>
Introduce business (primary motion)	"I move that..."	No	Yes	Yes	Yes	Majority
Amend a motion	"I move that this motion be amended by..."	No	Yes	Yes	Yes	Majority
End debate	"I move the previous question."	No	Yes	No	No	Two-thirds
Request information	"Point of information."	Yes	No (urgent)	No	No	No vote
Verify a voice vote	"I call for division of the House."	No	No	No	No	No vote
Complain about noise, room temperature, smoking	"Question of privilege."	Yes	No	No	No	Chair decides
Object to procedure or to a personal affront	"Point of order."	Yes	No	No	No	Chair decides
Lay aside an issue temporarily because of emergency	"I move to lay on the table ..."	No	Yes	No	No	Majority
Take up a matter previously tabled	"I move to take from the table..."	No	Yes	No	No	Majority
Consider something out of scheduled order	"I move to suspend the rules to consider..."	No	Yes	No	No	Two-thirds
Vote on a ruling by the Chair	"I appeal the decision."	Yes	Yes	Yes	No	Majority
Postpone consideration of something	"I move we postpone this matter until..."	No	Yes	Yes	Yes	Majority
Reconsider something already disposed of	"I move to reconsider the vote on issue X..."	Yes	Yes	Yes	No	Majority
Have something studied further	"I move to refer this to..."	No	Yes	Yes	Yes	Majority



We need your assistance in planning for the 2016-17 policy development process. Let us know what policy topics should be addressed by the 2017 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 2016-17 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>.



2016 House of Delegates

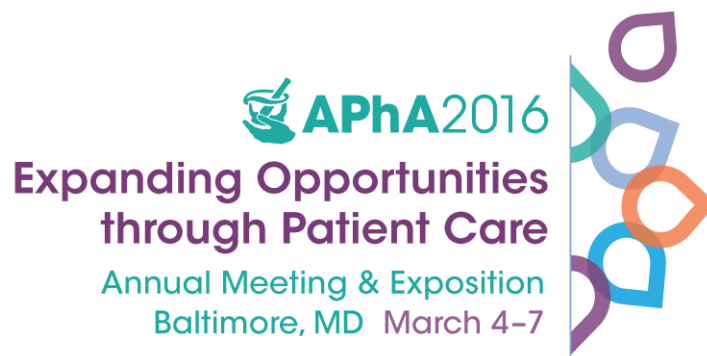
Report of the House Rules Review Committee

Committee Members

Betty J. Harris, Chair
Susan Bartlemay
Ally Dering-Anderson
Wendy Mobley-Bukstein
Brent Reed

Ex Officio Members

Theresa Tolle, Speaker of the House



2015-2016 APhA House Rules Review Committee Report

The 2015-2016 APhA House Rules Review Committee (HRRC) consists of the following APhA members and long-time Delegates:

Betty J. Harris, Chair
Orland, ME

Susie Bartlemay
Allen, TX

Wendy Mobley-Bukstein
Des Moines, IA

Ally Dering-Anderson
Lincoln, NE

Brent Reed
Baltimore, MD

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.

2015-2016 Specific Charges / Work Plan

This year, the following charges were assigned to the HRRC:

1. Observe the 2015 APhA House of Delegates proceedings, review House-related feedback, and make recommendations for improvement.
2. Review and approve, from a grammatical and copy-editing perspective, adopted policy from the 2015 APhA House of Delegates.
3. Review and approve the 2016 APhA House of Delegates schedule and make recommendations for improvement.
4. Review the APhA House of Delegates Rules of Procedure and make recommendations for improvement.

The HRRC met via conference call on April 17, 2015, May 1, 2015, and July 15, 2015, and made the following recommendations.

1. Observation of the 2015 APhA House of Delegates

Upon completing its review of the proceedings of the 2015 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 2015 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).

2. Review of Policy Adopted by the 2015 APhA House of Delegates

The HRRC reviewed, from a grammatical and copy-editing perspective, the policy language approved by the 2015 House of Delegates. Upon completing its review, the HRRC took the following action:

By CONSENT, the House Rules Review Committee approved the 2015 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.

- Delegate Education
 - The HRRC recommends the continued use of webinars to educate and engage APhA members in the Association's policy development process. The HRRC recommends additional marketing to members and Delegates regarding upcoming webinars, the scheduling of webinars outside of normal business hours, and the availability of webinars on-demand.
 - The HRRC recommends the inclusion of Committee of the Whole and general parliamentary procedure information in all Delegate orientation materials and in related webinars. The HRRC recommends that a hard copy Robert's Rule "cheat sheet" be included at every Delegate seat.
- New Business Items
 - The HRRC recommends that Delegates who submit new business items, within the specified deadline prior to the APhA Annual Meeting, be strongly encouraged to present the item during the New Business Open Hearing.
 - The HRRC recommends that Delegates who submit new business items provide a phone number at which they can be reached during the Annual Meeting, so that the New Business Review Committee may contact them for clarification or further information.
- Delegate Registration
 - The HRRC recommends that APhA staff explore the feasibility of having Delegate registration also available in the main registration area for the Annual Meeting.
- House of Delegates Materials
 - The HRRC recommends that all Delegate materials continue to be provided electronically unless otherwise requested by a Delegate. A limited number of Delegate materials will be made available onsite. Robert's Rules "cheat sheets" will be placed at each Delegate seat.
- Electronic Voting (*for votes requiring a 2/3 majority*)
 - The HRRC recommends that the electronic keypads be used as the primary method of voting whenever a two-thirds majority vote is required. It is also recommended that the number of votes cast be displayed on the screen and announced by the Speaker.
- Unfilled Delegation 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. Seats that remain unfilled for 3 consecutive years will be removed, beginning with the 2017 House.

- Amendments to Resolutions
 - The HRRC reviewed and discussed House Rule 7 (Amendments to Resolutions). Based on observations in the 2015 House and the previous process for secondary amendments, the HRRC recommends a change to House Rule 7 (see **Section 5**).
- Policy Review Process
 - The HRRC reviewed and discussed House Rule 10 (Policy Review Committee), including the Policy Review Committee's scope. Based on the discussion and feedback received from Delegates, the HRRC recommends a change to House Rule 10 (see **Section 5**).

4. Review of 2016 APhA House of Delegates Activities Schedule

The HRRC reviewed and evaluated the 2015 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 2016 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 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 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, ~~or 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, ~~if the amendment changes the original policy intent. Any such existing policy will be subject to review every five years or less. Starting with the 2014-2015 Policy Review Committee, and every 4 years from there (not on an even year when there is a Speaker election).~~ The Policy Review Committee shall meet annually and review any policy that has not been reviewed or had policies added in the past 4 years.

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

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 Betty J. Harris, Chair of the House Rules Review Committee.



2016 House of Delegates

Report of the Policy Review Committee

Part I

Policies last reviewed in 2011

- ❖ *Statements Organized by Recommendation*
- ❖ *Statements to Accompany New Business Items*

Part II

Policies related to the 2016 policy topics

Committee Members

Katherine Petsos, Chair
Sarah Barden
Andrew Bzowickyj
Megan Carroll
James Dvorsky
Brandi Hamilton
Adriane Irwin
Ronald Nosek
Kim Robbins

Ex Officio

Theresa Tolle, Speaker of the House

 **APhA2016**
**Expanding Opportunities
through Patient Care**
Annual Meeting & Exposition
Baltimore, MD March 4-7



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

PART I

RETAINED POLICY STATEMENTS

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

1996 Brand-Name Line Extensions

APhA opposes the use of the same brand name (or minor modifications of the same name) for prescription and non-prescription drug products containing different active ingredients.
(JAPhA NS36(6):396 June 1996) (Reviewed 2004) (Reviewed 2006)(Review 2011)

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

2002, 1984 Depiction of Pharmacists in Public Media

APhA supports the development of guidelines or standards to enhance the depiction of the pharmacy profession in all public media.
(Am Pharm NS24(7):60 July 1984) (JAPhA NS42(5: Suppl. 1:S62 September/October 2002) (Reviewed 2006)(Reviewed 2011)

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

1999 Direct-to-Consumer Advertising of Medications

1. APhA supports legislative and regulatory activities permitting direct-to-consumer advertising concerning medical or health conditions treatable by prescription or nonprescription drug products. These advertisements must conform to rules and regulations that assure complete, comprehensive and understandable information that informs consumers of potential benefits and risks of the product.
2. APhA opposes false or misleading advertising for prescription or nonprescription drugs or any promotional efforts that encourage indiscriminate use of medication.
3. APhA supports the availability of accurate information to consumers about medication use, and recognizes the responsibility of pharmacists to provide appropriate responses to consumer inquiries stimulated by direct-to-consumer advertising as a compensated pharmaceutical service. In addition, APhA recommends that health care professionals, including but not limited to pharmacists, receive new product information on direct-to-consumer advertising campaigns prior to this information being made available to consumers.
(JAPhA 39(4): 447 July/August 1999)(Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

2002 Investigation of Discount Card Issuer Practices

APhA encourages the Federal Trade Commission, the US attorney general or other appropriate agency to investigate misleading and deceptive marketing practices of issuers of discount cards.
(JAPhA NS42(5):Suppl. 1:S61 September/October 2002) (Reviewed 2006)(Reviewed 2011)

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

2004, 1977 Prescription Drug Advertising

APhA does not oppose the dissemination of price information to patients, by advertising or by any other means.
(JAPhA NS17:448 July 1977)(JAPhA NS44(5):551 September/October 2004)(Reviewed 2006)(Reviewed 2011)

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

1997 Use of the Word “Pharmacy” in Non-licensed Environments

APhA supports the establishment and enforcement of regulations through Boards of Pharmacy that restrict the use of the words “pharmacy”, “drug store”, “apothecary” or any other words or symbols of similar meaning or ~~type in signage and or the name of a business~~ names to entities in which the practice of pharmacy is conducted.

(JAPhA NS37:460 July/August 1997) (Reviewed 2002) (Reviewed 2006)(Reviewed 2011)

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

2011, 2002, 1996 Health Mobilization

APhA should continue to:

1. Emphasize its support for programs on disaster preparedness which involve the services of pharmacists (e.g., Medical Reserve Corps) and emergency responder registration networks [e.g., Emergency System for Advance Registration of Volunteer Health Professions (ESAR-VHP)].
2. Improve and expand established channels of communication between pharmacists; local, state and national pharmacy associations, boards and colleges of pharmacy and allied health professions.
3. Maintain its present liaison with the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services and continue to seek Office of Preparedness and Emergency Operations (OPEO) assistance through professional service contracts to further develop pharmacy’s activities in all phases of preparation before disasters
4. Encourage routine inspection of drug stockpiles and disaster kits by state boards of pharmacy.

(JAPhA N)S6:328. June, 1966) (JAPhA NS42(5) Suppl. 1:S62. September/October 2002) (Reviewed 2006) (JAPhA NS51(4) 483;July/August 2011

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

2006, 2002, 1971 Model Disaster Plan for Pharmacists

1. The committee recommends that APhA develop a disaster plan for the guidance of pharmacy organizations in responding to the needs of pharmacists who experience losses from disasters and that this model plan be disseminated to state associations for their reference.
2. The committee recommends that APhA cooperate with associations representing pharmaceutical manufacturers, wholesale distributors, and others in the pharmaceutical supply system in developing a mechanism to facilitate the communication of information about the losses incurred by pharmacists as a result of disasters. Those firms that make it a practice to replace uninsured losses of inventories of their products could do so promptly and efficiently so that normal pharmaceutical services to the affected community are resumed as soon as possible.

(JAPhA NS11:256 May 1971) (JAPhA NS42(5): Suppl 1:S62, September/October 2002) (JAPhA NS46(5):562 September/October 2006)(Reviewed 2011)

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

2004, 1984 Issuing of Drugs by Non-pharmacists

APhA supports issuing drug products to patients by non-pharmacists under the control and direction of pharmacists.

(Am Pharm NS24(7):60 July 1984) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)

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

1979 Out of State Prescription Orders

APhA supports the repeal of state laws, which prohibits the dispensing of an otherwise legal prescription order, issued by a prescriber licensed in another state.
(Am Pharm NS19(7):67 June 1979) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

1997 DEA Employment Waiver

APhA urges the Drug Enforcement Administration, in processing employment waiver requests, to defer to the decisions of state boards of pharmacy related to the licensure of pharmacists suffering from alcohol and other chemical dependencies.
(JAPhA NS37(4):459 July/August 1997)(Reviewed 2003) (Reviewed 2006)(Reviewed 2011)

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

2003 Drug Addiction/Chemical Dependency Education

APhA urges pharmacists and pharmacy students to become educated in the recognition and treatment of drug addiction and chemical dependency.
(JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2006)(Reviewed 2011)

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

1990 Drug Testing in the Workplace

APhA endorses the concept of the "Drug Free Workplace" and recommends that where drug testing is performed in the workplace it be conducted in conjunction with an employee assistance program.
(Am Pharm NS30(6):45 June 1990)(Reviewed 2003) (Reviewed 2006)(Reviewed 2011)

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

2011, 2005, 2002 Funding for Pharmacist Recovery Programs

APhA supports and encourages a cooperative effort among state and national pharmacy associations, state boards of pharmacy, and state legislative bodies to authorize, develop, implement and maintain mechanisms for the comprehensive funding of state recovery programs for pharmacists, student pharmacists and pharmacy technicians.
(JAPhA NS42(5):Suppl. 1:S61 September/October 2002) (JAPhA NS45(5):559 September/October 2005) (Reviewed 2006)(Reviewed 2010)
(JAPhA NS51(4) 483;July/August 2011)

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

2003, 1972 Methadone Used as Analgesic and Antitussive

APhA encourages developers of methadone programs to place pharmacists in charge of their drug distribution and control systems.
(JAPhA NS12:308 June 1972) (JAPhA NS43(5):Suppl. 1:S58 September/October 2003) (Reviewed 2006)(Reviewed 2011)

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

2005, 2003, 1982 Pharmacists with Impairments that Affect Practice

1. APhA advocates that pharmacists should not practice while subject to physical or mental impairment due to the influence of drugs -- including alcohol -- or other causes that might adversely affect their abilities to function properly in their professional capacities.
2. APhA supports establishment of counseling, treatment, prevention, and rehabilitation programs for pharmacists and student pharmacists who are subject to physical or mental impairment due to

the influence of drugs – including alcohol – or other causes, when such impairment has potential for adversely affecting their abilities to function in their professional capacities.

(Am Pharm NS22(7):32 July 1982) (JAPhA NS43(5):Suppl. 1:S58 September/October 2003) (JAPhA NS45(5):559 September/October 2005)(Reviewed 2006)(Reviewed 2011)

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

1981 Removal of Hallucinogenic Solvents from Paints, Sprays, and Glues

APhA supports the denaturing of abused products containing hallucinogens by appropriate means, such as the addition of harmless chemicals with obnoxious scents or with the ability to produce nausea when the products are abused, but not when used as directed.

(Am Pharm NS21(5):40 May 1981)(Reviewed 2006)(Reviewed 2011)

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

2003, 1971 Security — Pharmacists' Responsibility

APhA encourages pharmacists to voluntarily remove all proprietary drug products with potential for abuse or adverse drug interactions from general sales areas and to make their dispensing the personal responsibility of the pharmacist.

(JAPhA NS11:267 May 1971)(JAPhA NS43(5):Suppl. 1:S58 September/October 2003)(Reviewed 2006)(Reviewed 2011)

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

2004, 1966 Distribution Programs: Circumvention of the Pharmacist

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

(JAPhA NS6:293 June 1966) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)

20. 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.

(JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)

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

1985 Pharmaceutical Pricing

APhA supports a system of equal opportunity with the same terms, conditions, and prices available for all pharmacies.

(Am Pharm NS25(5):52 May 1985) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

1978 Post-Marketing Requirements (Restricted Distribution)

APhA opposes any legislation that would grant FDA authority to restrict the channels of drug distribution for any prescription drug as a condition for approval for marketing the drug under approved labeling.

(Am Pharm NS18(8):30 July 1978) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

1994 Product Licensing Agreements and Restricted Distribution

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

(Am Pharm NS34(6):55 June 1994) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

2004, 1971 Single Dose Containers for Parenteral Use

APhA supports packaging all drugs intended for parenteral use in humans in single-dose containers, except where clearly not feasible.

JAPhA NS11:270 May 1971) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)

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

1983 Pharmaceutical Alternates

APhA supports recognition of the pharmacist's role in the selection of pharmaceutical alternates (i.e., drug products containing the same therapeutic moiety, but differing in salt, ester, or comparable physical/chemical form or differing in dosage form)

(Am Pharm NS23(6):52 June 1983) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

2011 Potential Conflicts of Interest in Pharmacy Practice

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

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

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

2011, 2004, 1995 Product Recall Policy

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

(Am Pharm NS35(6):38 June 1995) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006) (JAPhA NS51(4) 483;July/August 2011)

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

2003, 1997 Continued Competence Assessment Examination

1. APhA should develop, in cooperation with other state and national associations, a voluntary process for self-assessing pharmaceutical care competence.
2. APhA opposes regulatory bodies utilizing continuing competence examinations as a requirement for renewal of a pharmacist's license.
3. APhA supports programs that measure and evaluate pharmacist competence based on established valid standards.

(JAPhA NS37(4): 460 July/August 1997) (JAPhA NS43(5):Suppl. 1:S58 September/October 2003)(Reviewed 2005) (Reviewed 2006)(Reviewed 2008)(Reviewed 2011)

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

2003, 1974 Continuing Education

APhA strongly endorses continuing education for pharmacists.

(JAPhA NS14:494 September 1974) (JAPhA NS43(5): Suppl. 1:S58 September/October 2003) (Reviewed 2005) (Reviewed 2006)(Reviewed 2011)

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

2005, 1992 Cross-Discipline Accreditation of Continuing Education

1. APhA supports the acceptance, for pharmacy continuing education credit of relevant, quality programs offered by other health-related continuing education providers.
2. APhA supports the acceptance of relevant programs offered by the Accreditation Council for Pharmacy Education (ACPE)-accredited providers to meet continuing education requirements in other health disciplines.

(Am Pharm NS32(6):515 June 1992) (Reviewed 2003) (JAPhA NS45(5):560 September/October 2005) (Reviewed 2006)(Reviewed 2011)

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

2011, 2003 Distance Education in First Professional Pharmacy Degree Programs

1. Distance education components of first professional pharmacy degree programs must be constructed in a way to assure socialization into the profession and understanding the ethos and essence of the profession, as such development is primarily derived through practical experience and interaction with faculty, colleagues and patients.
2. APhA expects the Accreditation Council for Pharmacy Education to develop, maintain, and enforce applicable standards to ensure students trained in distance education programs achieve the same educational and professional competencies as students in on-site programs.

(JAPhA NS43(5):Suppl.1:S56 September/October 2003) (Reviewed 2006) (JAPhA NS51(4) 482;July/August 2011)

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

1991 Doctor of Pharmacy Attainment through Non-traditional Mechanisms

1. APhA encourages schools and colleges of pharmacy to consider, in their strategic planning process, offering non-traditional, post-baccalaureate, doctor of pharmacy degree programs. Issues to be considered in such planning should include at least the following:

- (a) entry requirements;
- (b) educational and financial resources; and
- (c) competency evaluation for course credit.

2. APhA recommends that non-traditional, doctor of pharmacy degree programs have competency outcomes for graduates equal to those in traditional programs.

(Am Pharm NS31(6):28 June 1991) (Reviewed 2003) (Reviewed 2006)(Reviewed 2011)

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

1993 Payment System Reform Curriculum

APhA encourages the colleges and schools of pharmacy to incorporate the concept of payment system reform throughout the curricula for all professional programs, and should work with pharmacy organizations to ensure the integration of these concepts into practitioners' continuing development.

(Am Pharm NS33(7):54 July 1993) (Reviewed 2003) (Reviewed 2006)(Reviewed 2011)

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

1975 Pharmacists' Responsibility for Continuing Competence

APhA advocates that pharmacists maintain their professional competence throughout their professional careers.

(JAPhA NS15:336. June, 1975) (Reviewed 2001) (Reviewed 2003)(Reviewed 2005) (Reviewed 2006)(Reviewed 2011)

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

1984 Primary and Secondary Education in Science, Mathematics, and English

APhA supports efforts to improve education at the primary and secondary school levels, particularly in the areas of science, mathematics, and English.

(Am Pharm NS24(7):60 July 1984) (Reviewed 2003) (Reviewed 2006)(Reviewed 2011)

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

1988 Professional Ethics in Educational Curricula and Practice

APhA supports the incorporation of professional ethics instruction in pharmacy curricula and post-graduate continuing education and training.

(Am Pharm NS28(6):394 June 1988) (Reviewed 2003) (Reviewed 2005) (Reviewed 2006)(Reviewed 2011)

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

1982 Use of Academic and Continuing Education Credit

1. APhA supports the award of continuing education credit for the successful completion of academic credit courses within the scope of pharmacy practice under circumstances which preserve the integrity of both the academic and the continuing education credit.
2. APhA endorses the development and implementation by colleges of pharmacy and other appropriate organizations, of standards and mechanisms by which academic credit can be awarded for successful completion of continuing education courses under circumstances which preserve the integrity of the academic credit.

(Am Pharm NS22(7):33 July 1982) (Reviewed 2003) (Reviewed 2005) (Reviewed 2006)(Reviewed 2011)

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

1994 The Scientific Implications of Health Care Reform

1. APhA advocates that the public and private sectors maintain or increase their level of commitment to assure adequate resources for both basic and applied research within a reformed health care system.
2. APhA encourages the public and private research communities to preferentially expend resources for the discovery and development of new drugs and technologies that provide substantive, innovative therapeutic advances.

3. APhA advocates an increased emphasis on outcomes research in all areas of health services, including drug and disease-specific research encompassing clinical, economic, and humanistic dimensions (e.g., quality of life, patient satisfaction, ethics) and advocates for action related to conclusions for such research.
 4. APhA encourages interdisciplinary collaboration in research efforts within and between the public and private research communities.
- (Am Pharm NS34(6):55 June 1994)(Reviewed 2004)(Reviewed 2005)(Reviewed 2010)(Reviewed 2011)

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

2004, 1965 Guidelines for Physician Ownership

APhA supports efforts to develop guidelines on physician ownership of pharmacies due to the inherent conflict of interest.

(JAPhA NS5:276 May 1965) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010) (Reviewed 2011)

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

2011, 2004, 1963 Pharmacists and Other Health Practitioners and Pharmacists: Relationships and Compensation Among Health Care Practitioners

APhA opposes any method which provides an inappropriate sharing of compensation between the prescriber and dispenser.

(JAPhA NS3:298 June 1963) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010) (JAPhA NS51(4) 484; July/August 2011)

NOTE: The modification of policy titles does not require approval of the House.

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

2004, 1975 Other Health Care Professional Organizations

APhA supports continuing joint action with other health care and professional organizations.

(JAPhA NS15:331-333 June 1975) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010)(Reviewed 2011)

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

1989 The Joint Commission

1. APhA supports increased interaction with The Joint Commission regarding accreditation standards and procedures pertaining to pharmacy and therapeutics.
2. APhA supports pharmacy representation on appropriate The Joint Commission professional and technical advisory committees.

(Am Pharm NS29(7)464 July 1989) (Reviewed 2004) (Reviewed 2009) (Modified 2010)(Reviewed 2011)

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

2008 Pharmacy Compounding Accreditation

1. APhA reaffirms the 1992 Compounding Activities of Pharmacists policy, which states that APhA affirms that compounding pursuant to or in anticipation of a prescription or diagnostic preparation order is an essential part of health care that is the prerogative of the pharmacist.
2. APhA supports compounding as defined by the Pharmacy Compounding Accreditation Board (PCAB) as a means to meet patient drug therapy needs.
3. APhA opposes compounding when identical medications are commercially and readily available in strength and dosage form to meet patient drug therapy needs.

4. APhA asserts that compounding is subject to regulations and oversight from state boards of pharmacy. APhA urges state boards of pharmacy to identify and take appropriate action against entities who are illegally manufacturing medications under the guise of compounding.
5. APhA supports accreditation of compounding sites by PCAB to ensure patient safety. APhA encourages state boards of pharmacy to recommend accreditation for those sites that engage in more than basic non sterile compounding as defined by PCAB.
6. APhA supports the development of education, training and recognition programs that enhance pharmacist and student pharmacist knowledge and skills to engage in compounding beyond basic, non sterile preparations as defined by PCAB.
7. APhA encourages the exploration of a specialty certification in the area of compounding through the Board of Pharmaceutical Specialties (BPS).

(JAPhA NS48(4):470 July/August 2008) (Reviewed 2009)(Reviewed 2011)

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

2011 Pharmacy Practice Accreditation

1. APhA should lead the creation of consensus-based, pharmacy profession-developed accreditation standards and methods of evaluation to optimize the quality and safety of patient care and promote best practices.
2. APhA urges that accrediting bodies use profession-developed standards for pharmacy.
3. APhA supports only those pharmacy accreditation processes that are voluntary, transparent, consensus-based, reasonably executable, and affordable, while avoiding duplication and barriers to patient care.
4. APhA opposes mandatory pharmacy accreditation.
5. APhA shall assume the leadership role among stakeholders on the design and implementation of an appropriate process for any new pharmacy accrediting program.
6. APhA supports the appropriate use of data gathered from pharmacy practice monitoring processes to facilitate the advancement of pharmacy practice and quality of patient care.

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

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

2002 Professional Practice Regulation

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

(JAPhA NS42(5):Suppl. 1:S60 September/October 2002) (Reviewed 2007) (Reviewed 2008)(Reviewed 2011)

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

1979 Child Abuse Reporting

APhA urges pharmacists to report all suspected cases of child abuse to proper authorities.

(Am Pharm NS19(7):69 June 1979) (Reviewed 2006)(Reviewed 2011)

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

1995 Continuum of Patient Care

1. APhA advocates and will facilitate pharmacists' participation in the continuum of patient care. The continuum of patient care is characterized by the interdisciplinary care provided a patient through a series of organized, connected events or activities independent of time and practice site, in order to optimize desired therapeutic outcomes.
2. APhA will facilitate pharmacists' participation in the continuum of patient care by:
 - a. Achieving recognition for the pharmacist as a primary care provider;
 - b. Securing access for pharmacists to patient information systems, including creation of the necessary software for the purpose of record maintenance of cognitive services provided by pharmacists;
 - c. Developing means and methods to establish and enable pharmacists' direct participation in the continuum of patient care.

(Am Pharm NS35(6):36 June 1995) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

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

1987 Cost-effectiveness of Drug Products and Pharmacy Services

APhA supports the development of programs which educate pharmacy's several publics about the cost-effectiveness of drug products and related comprehensive pharmacists services.

(Am Pharm NS27(6):422 June 1987) (Reviewed 2004) (Reviewed 2010)(Reviewed 2011)

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

2005 Cultural Competence

1. Recognizing the diverse patient population served by our profession and the impact of cultural diversity on patient safety and medication use outcomes, APhA encourages pharmacists to continually strive to achieve and develop cultural awareness, sensitivity, and cultural competence.
2. APhA shall facilitate access to resources that assist pharmacists and student pharmacists in achieving and maintaining cultural competence relevant to their practice.

(JAPhA NS45(5):554 September/October 2005) (Reviewed 2006)(Reviewed 2011)

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

2005 Patient Safety

1. Patient safety is influenced by patients, caregivers, health care providers, and health care systems. APhA recognizes that improving patient safety requires a comprehensive, continuous, and collaborative approach to health care.
2. APhA should promote public and provider awareness of and encourage participation in patient safety initiatives.
3. APhA supports research on a more effective, proactive, and integrated health care system focused on improving patient safety. APhA encourages implementation of appropriate recommendations from that research.

(JAPhA NS45(5):554 September/October 2005) (Reviewed 2009)(Reviewed 2011)

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

2003, 1992 The Pharmacist's Role in Therapeutic Outcomes

1. APhA affirms that achieving optimal therapeutic outcomes for each patient is a shared responsibility of the health care team.

2. APhA recognizes that a primary responsibility of the pharmacist in achieving optimal therapeutic outcomes is to take an active role in the development and implementation of a therapeutic plan and in the appropriate monitoring of each patient.

(Am Pharm NS32(6):515 June 1992) (JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2007) (Reviewed 2009) (Reviewed 2010)(Reviewed 2011)

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

1971 Prescription Department Security

The committee recommends that APhA support state legislation to require that a prescription department must be secured whenever the pharmacist or persons authorized by the pharmacist are not present.

(JAPhA NS11:267 May 1971)(Reviewed 2006)(Reviewed 2011)

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

1996 Quality Assurance and Improvement in Pharmacy Practice

1. APhA recommends that all pharmacists incorporate principles and tools available to continually improve the quality of patient care and management activities in their practices.
2. APhA recommends that content on principles and tools available to continually improve the quality of patient care and management practices be incorporated into pharmacy school curricula and into post-graduate education for pharmacists.
3. APhA supports appropriate evaluation and recognition of providers of pharmaceutical care.

(JAPhA NS36(6):395 June 1996) (Reviewed 2004) (Reviewed 2010)(Reviewed 2011)

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

2003, 1993 The Pharmacist's Role with Diagnostic Drugs in Therapeutic Outcomes

APhA recognizes that it is a responsibility of the pharmacists to take an active role in the selection and use of diagnostic drugs as an integral component in the development and implementation of a patient's therapeutic plan.

(Am Pharm NS33(7):56 July 1993) (JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2007) (Reviewed 2009)(Reviewed 2010)((Reviewed 2011)

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

2011, 1996 Fluoridation of Water Supplies

APhA reaffirms its 1954 position in support of appropriate fluoridation of water supplies and encourage pharmacists to assist in implementing such programs in their local communities.

(JAPhA NS6:293 June 1966) (Reviewed 2005) (Reviewed 2009)(JAPhA NS51(4) 484;July/August 2011)

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

1986 Reye Syndrome

APhA supports all initiatives which enhance public education about the potential relationship between Reye Syndrome and oral and rectal salicylate-containing products, including settings where pharmacists are not available for consultation.

(Am Pharm NS26(6):419 June 1986) (Reviewed 2006)(Reviewed 2011)

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

2011, 1995 Measuring the Quality of Patient Care

1. APhA believes that quality assessment measures must evaluate the accessibility, acceptability, and technical quality of pharmacy services, as well as the patient-centered and economic outcomes of patient care. These measures must consider the perspectives of patients, pharmacists, and other health care providers.

2. APhA believes quality assessment measures of patient care should be tested for validity and reliability in various pharmacy practice settings prior to widespread application.
3. APhA should develop tools and/or programs that enable pharmacists to apply quality assessment measures to their delivery of patient care.
4. APhA should promote efforts to educate patients, pharmacists, other health care providers, payers, policy makers, and other interested parties on the appropriate use of quality assessment measures to evaluate and improve the delivery of patient care.

(Am Pharm NS35(6):37 June 1995) (Reviewed 2006 – Statement 1 archived in 2006)((JAPhA NS51(4) 484;July/August 2011)

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

2011, 1994 APhA's Role in the Development and Support of New Payment Systems

1. APhA should continue its work with pharmacy benefits' managers and other private and public payers to develop innovative pharmacy benefit designs and compensation strategies for pharmacists' services.
2. APhA will endorse benefit design concepts that recognize and compensate pharmacists for their cognitive services to maximize therapeutic outcomes.

(Am Pharm NS34(6):58 June 1994) (Reviewed 2005)(Reviewed 2009) (Reviewed 2010((JAPhA NS51(4) 484;July/August 2011)

59. 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.

(Am Pharm NS33(7):53 July 1993) (Reviewed 2005) (Reviewed 2009)(Reviewed 2011)

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

1980 Nuclear Pharmacy Regulations

1. APhA supports the concept of state boards of pharmacy retaining their authority to regulate all aspects of professional pharmacy practice including nuclear pharmacy practice.
2. APhA urges state boards of pharmacy to promptly adopt appropriate rules and regulations for the practice of nuclear pharmacy, using the NABP Model Regulations for the Licensure of Nuclear Pharmacies as a model.

(Am Pharm NS20:69 July 1980) (Reviewed 2006)(Reviewed 2011)

AMENDED POLICY STATEMENTS

Underlined designate a recommendation to make an amendment that does not change the intent of the policy statement.

61. The Committee recommends **AMENDING** the following policy statement as written.

2011, 2002, 1963 Role of the Pharmacist in National Defense

APhA endorses the position that the pharmacist, as a member of the health care team, has the ethical responsibility to assume a role in disaster preparedness and emergency care operations. These responsibilities include:

1. Pharmacists, by their education and training as medication experts, should be involved intimately in all elements of the procurement, storage, handling, compounding, and dispensing of drugs and supplies in planning for as well as during any national emergency.
2. Pharmacists, by their education in anatomy, physiology, and pharmacology, are readily adaptable to assist in the emergency medical treatment of patients and for training the public in medical self-help.
3. Pharmacists, by their constant contact with the members of the health team, as well as a significant portion of their communities, provide the potential for coordinating preparedness measures, and establishing meaningful standby emergency operational plans.

In view of these responsibilities, it shall be the further policy of APhA

1. To cooperate with all responsible agencies and departments of the federal government.
2. To provide leadership and guidance for the profession of pharmacy by properly assuming its role with other health profession organizations at the national level (e.g., ~~including~~ American Medical Association, American Hospital Association, American Dental Association, American Nurses Association, and American Veterinary Medical Association).
3. To assist and cooperate with all national specialty pharmaceutical organizations to provide assistance and coordination in civil defense matters relevant to their area of concern.
4. To encourage and assist the state and local pharmacy associations in their efforts to cooperate with the state and local governments as well as the state and local health profession organizations in order that the pharmacist may assume his proper place in civil defense operations.
5. To provide leadership and guidance so that individual pharmacists can contribute their services to civil defense and disaster planning, training, and operations in a manner consistent with ~~his~~ their position as a member of the health team.

(JAPhA NS3:330 June 1963) (JAPhA NS42(5): Suppl. 1:S62 September/October 2002) (Reviewed 2006)(Reviewed 2010) (JAPhA NS51(4) 483;July/August 2011)

COMMENTS: The Policy Review Committee reviewed the policy statements and recommends AMENDING statement #2 of the second section to replace “including” with “e.g.” and statement #5 to replace “his” with “their” to reflect proper terminology.

62. The Committee recommends **AMENDING** the following policy statement as written.

2005, 1995 Professional Development of Student Pharmacists

1. APhA believes that it is essential to integrate professionalism throughout a student pharmacist’s educational experience.

2. APhA will assist schools and colleges of pharmacy to develop and utilize recruitment materials that emphasize the professional role and responsibilities associated with the provision of pharmaceutical care.
3. APhA ~~encourages~~ supports schools and colleges of pharmacy ~~to~~ interviewing candidates during the admissions process to assess their characteristics for the potential for development of professional attitudes and behaviors.
4. APhA recommends that schools and colleges of pharmacy administer the model pledge of professionalism, as developed by the APhA-ASP/American Association of Colleges of Pharmacy Council of Deans Task Force on Professionalism, to all student pharmacists.
5. APhA encourages schools and colleges of pharmacy and the American Association of Colleges of Pharmacy to develop and implement ongoing programs for faculty, staff, preceptors, and other mentors to enhance their ability to serve as role models and teach professionalism.
6. APhA supports the continuation of ~~will develop and institute~~ a forum for faculty, students, preceptors, and others to establish and foster mentor relationships.

(Am Pharm NS35(6):36 June 1995) (Reviewed 2003) (JAPhA NS45(5):554 September/October 2005) (Reviewed 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee reviewed the policy statements and recommends AMENDING statement #3 to replace “encourages” with “supports” and change “to interview” with “interviewing” along with amending statement #6 to replace “will develop and institute” with “supports the continuation of” as this terminology more accurately describes APhA’s role related to the professional development of student pharmacists.

63. The Committee recommends **AMENDING** the following policy statement as written.

2011 Pharmacists as Providers Under the Social Security Act

APhA supports changes to the Social Security Act to allow pharmacists to be recognized and paid as providers of patient care services, ~~including but not limited to medication therapy management.~~

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

COMMENTS: The Policy Review Committee reviewed this policy statement and recommends removing “, including but not limited to medication therapy management”. This modification would better align the activities by pharmacists and broaden the scope of services provided.

64. The Committee recommends **AMENDING** the following policy statement as written.

1994 Pharmacy Services Benefits in Health Care Reform

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

1. Universal coverage for pharmacy service benefits that include both medications and pharmacists’ services;
2. Specific provisions for the access to and payment for pharmacists’ patient care services ~~pharmaceutical care services, including, but not limited to, patient compliance and preventive care, medication therapy management (MTM) of complex and high-risk patients, health education, drug regimen review, and drug utilization review;~~
3. A single set of pricing rules, eliminating class-of-trade distinctions, for medications, medication delivery systems, and other equipment so that no payer, patient, or provider is disadvantaged by cost shifting;

4. The right for every American to choose his/her own provider of medications and pharmacists' services and for all pharmacists to participate in the health plans of their choice under equally applied terms and conditions;
 5. Quality assurance mechanisms to improve and substantiate the effectiveness of medications and health services;
 6. Information and administrative systems designed to enhance patient care, eliminate needless bureaucracy, and provide patients and providers price and quality information needed to make informed patient-care decisions;
 7. Relief from antitrust laws and regulations to enable pharmacists to establish systems that balance provider needs relative to corporate and governmental interests;
 8. Reform in the professional liability system, including caps on non-economic damages, attorneys' fees, and other measures;
 9. Representation on the controlling board of each plan by an active health care practitioner from each discipline within the scope of the plan; and
 10. Recognition of the pharmacist's role in delivering primary health care services.
- (Am Pharm NS34(6):58 June 1994) (Reviewed 2004) (Reviewed 2010) (Reviewed 2011)

COMMENTS: The Policy Review Committee recommends AMENDING statement #2 to replace "pharmaceutical care services, including but not limited to, patient compliance and preventive care, medication therapy management (MTM) of complex and high risk patients, health education, drug regimen review, and drug utilization review" with "pharmacists' patient care services". This modification broadens the policy and recognizes the expanded scope of services offered by pharmacists.

65. The Committee recommends **AMENDING** the following policy statement as written.

2004, 1965 Mental Health Programs

APhA supports pharmacists' participation in the development and implementation of all aspects of mental health programs so that the most appropriate care is offered to patients with mental health needs ~~special needs and problems of the mentally ill can be effectively met.~~

(JAPhA NS5:274 May 1965) (JAPhA NS44(5):551 September/October 2004)(Reviewed 2010)(Reviewed 2011)

COMMENTS: The Policy Review Committee reviewed the policy statement and recommends AMENDING the statement to replace "special needs and problems of the mentally ill can be effectively met" with "most appropriate care is offered to patients with mental health needs". This modification is more consistent with contemporary terminology.

66. The Committee recommends **AMENDING** the following policy statement as written.

2006 Tobacco/Nicotine Use Data Entry Field in Pharmacy Patient Records

APhA supports standardizing patient records and clinical decision support tools (including pharmacy dispensing systems) to collect, document, and utilize information regarding the patient's tobacco/nicotine use.

(JAPhA NS46(5):561 September/October 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee recommends AMENDING this policy statement to include the term "Nicotine" to reflect contemporary terminology.

ARCHIVED POLICY STATEMENTS

67. The Committee recommends **ARCHIVING** the following policy statement as written.

1980 Non-prescription Drug Advertising

1. APhA supports a legislative or regulatory requirement that advertising of non-prescription drugs directed to the health care professions identify all active and inactive ingredients, including disclosure of the quantitative amounts of all physiologically active ingredients.
2. APhA supports disclosure of all therapeutically active ingredients of non-prescription drugs in advertising directed to the public

(Am Pharm NS20(7):62 July 1980) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee recommends **ARCHIVING** this policy because it is no longer relevant. FDA requirements for OTC labeling of active ingredients was enacted in May 2005.

68. The Committee recommends **ARCHIVING** the following policy statement as written.

1992 Balanced Education for Pharmacists

1. APhA encourages schools and colleges of pharmacy to continue to develop educational requirements to ensure the provision of a balanced, general education in order to graduate educated citizens and competent, health care professionals.
2. APhA supports development of admission processes by schools and colleges of pharmacy that ensure ~~assure~~ that students possess qualities necessary to become educated citizens and competent, health care professionals.

(Am Pharm NS32(6):515 June 1992) (Reviewed 2001) (Reviewed 2003) (Reviewed 2005) (Reviewed 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee recommends **ARCHIVING** this policy statement as the Committee felt that the Accreditation Council for Pharmacy Education has successfully implemented these policies and regulations. This policy is no longer necessary to have listed as active policy for the Association.

The Policy Review Committee identified the following policy statements as needing an amendment that changes the intent. If the associated NBI is not adopted by the House then the recommendations in this report stand, as approved by the House of Delegates.

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

2006 Conversion of Nonprescription Products Into Drugs of Abuse

1. APhA supports legislative, regulatory, and private sector efforts that include input from pharmacists to balance the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.
2. APhA supports consumer sales limits of nonprescription drug products that may be illegally converted into drugs for illicit use.
3. APhA encourages education of all personnel involved in the distribution chain of nonprescription products concerning the potential for certain products to be illegally converted into drugs for illicit use.
4. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.

(JAPhA N46(5):561 September/October 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee (PRC) intends to submit a New Business Item (NBI) to combine policy statements (#69) “*2006 Conversion of Nonprescription Products Into Drugs of Abuse*” and (#70) “*2005 Efforts to Limit Methamphetamine Access*” into one cohesive, comprehensive whole policy. The committee recommends **RETAINING** this policy statement as written unless a revised statement is adopted as a NBI by the House. If the policy statement is **RETAINED** then the PRC recommends referring this policy to the 2016-17 Policy Review Committee for additional review.

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

2005 Efforts to Limit Methamphetamine Access

1. APhA supports legislation that balances the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.
2. APhA supports stringent enforcement of criminal laws against individuals who engage in the illegal trafficking of methamphetamine and methamphetamine precursors.
3. APhA supports retail sales limits of non-prescription products that contain methamphetamine precursors to prevent diversion.
4. APhA supports education of employees involved in the distribution chain of methamphetamine precursors about diversion, methamphetamine abuse and prevention of abuse. APhA supports patient/consumer education of consequences of methamphetamine abuse.
5. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.

(JAPhA NS45(5):555 September/October 2005)(Reviewed 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee (PRC) intends to submit a New Business Item (NBI) to combine policy statements (#69) “*2006 Conversion of Nonprescription Products Into Drugs of Abuse*” and (#70) “*2005 Efforts to Limit Methamphetamine Access*” into one cohesive, comprehensive policy. The committee recommends **RETAINING** this policy statement as written unless a revised statement is adopted as a NBI by the House. If the policy statement is **RETAINED** then the PRC recommends referring this policy to the 2016-17 Policy Review Committee for additional review.

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

2003, 1987 Drug Abuse Education

APhA supports comprehensive drug abuse prevention programs consisting of education and rehabilitation.

(Am Pharm. NS27(6):424 June 1987) (JAPhA NS43(5): Suppl. 1:S58 September/October 2003) (Reviewed 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee (PRC) intends to submit a New Business Item (NBI) to clarify the intention of this policy statement as it relates to APhA's support of prevention and rehabilitation programs. The committee recommends **RETAINING** this policy statement as written unless a revised statement is adopted as a NBI by the House. If the policy statement is **RETAINED** then the PRC recommends referring this policy to the 2016-17 Policy Review Committee for additional review.

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

1990 Legalization or Decriminalization of Illicit Drugs

APhA opposes legalization or decriminalization of the possession, sale, distribution, or use of drug substances for non-medicinal uses.

(Am Pharm NS30(6):46 June 1990) (Reviewed 2003)(Reviewed 2006)(Reviewed 2011)

COMMENTS: The Policy Review Committee (PRC) intends to submit a New Business Item (NBI) to include alternative pathway language for the treatment and rehabilitation of individual's arrested/charged/convicted of illicit drug-related offenses. The committee recommends **RETAINING** this policy statement as written unless a revised statement is adopted as a NBI by the House. If the policy statement is **RETAINED** then the PRC recommends referring this policy to the 2016-17 Policy Review Committee for additional review.

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

2011, 1995 Adequacy of Directions for Use on Prescriptions and Prescription Orders

1. APhA recommends that all professions with prescriptive authority address the issue of prescribers' responsibility for specific instructions to the pharmacist and the patient in all prescription orders.
2. APhA affirms the pharmacist's responsibility, as the patient's advocate, to obtain and communicate adequate directions for use of medications.

(JAPhA NS51(4) 484;July/August 2011)

COMMENTS: The Policy Review Committee (PRC) intends to submit a New Business Item (NBI) to add language concerning the prescriber's responsibility to provide clarification on prescription orders. The Committee recommends **RETAINING** this policy statement as written unless a revised statement is adopted as a NBI by the House. If the policy statement is **RETAINED** then the PRC recommends referring this policy to the 2016-17 Policy Review Committee for additional review.

PART II

highlighting designates a recommendation to archive the statement as historical.

Biologic, Biosimilar, and Interchangeable Biologic Drug Products

Related APhA Policy

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

2012, 2007 Biologic Drug Products

1. APhA encourages the development of safe, effective, and affordable therapeutically equivalent generic/biosimilar versions of biologic drug products, including clinical trials that assess safety.
2. APhA encourages the FDA to develop a scientifically based process to approve therapeutically equivalent generic/biosimilar versions of biologic drug products.
3. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.
4. APhA should initiate educational programs for pharmacists and other health care professionals concerning the determination of therapeutic equivalence of generic/biosimilar versions of biologic drug products.

(JAPhA NS45(5):580 September-October 2007))(JAPhA NS52(4) 458 July/August 2012)

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

1991 Biotechnology

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

(Am Pharm NS31(6):29 June 1991)(Reviewed 2004)(Reviewed 2007)(Reviewed 2010)

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

2005, 1988 Pharmaceutical Biotechnology Products

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

(Am Pharm NS28(6):394 June 1988) (JAPhA NS45(5):559 September/October 2005)(Reviewed 2006) (Reviewed 2007) (Reviewed 2010)

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

2004, 1971 Anti-substitution Laws: Pharmacists' Responsibility

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

(JAPhA NS11:260. May, 1971) (JAPhA NS 44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)

Point-of-Care Testing

Related APhA Policy

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

2013, 2008, 1987 Sale of Home-use Diagnostic and Monitoring Products

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

(Am Pharm NS27(6):424 June 1987) (Reviewed 2003) (JAPhA NS48(4):470 July/August 2008) (JAPhA 53(4):366 July/August 2013)

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

2012, 20013 The Pharmacist's Role in Laboratory Monitoring and Health Screening

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

(JAPhA NS43(5)Suppl. 1:S58 September/October 2003) (Reviewed 2007) (Reviewed 2009) (Reviewed 2010) (JAPhA NS52(4) 460 July/August 2012) (Reviewed 2013)

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

2011 The Role and Contributions of the Pharmacist in Public Health

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

(JAPhA NS52(4) 482 July/August 2011) (Reviewed 2012)

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

1981 Pharmacist Training in Medical Technology

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

(Am Pharm NS21(5):40 May 1981) (Reviewed 2003) (Reviewed 2006) (Reviewed 2011)

9. The Committee recommends **ARCHIVING** the following policy statement as written.

1989 Pharmacy-based Screening and Monitoring Services

APhA supports projects that demonstrate and evaluate various pharmacy-based screening and monitoring services.

(Am Pharm NS29(7):463 July 1989) (Reviewed 2006) (Reviewed 2007)(Reviewed 2013)

COMMENTS: The Policy Review Committee recommends ARCHIVING this policy statement as the committee feels this objective has been accomplished and more contemporary and comprehensive policy exists.

Medication Optimization Services within the Patient Care Process

Related APhA Policy

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

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.

(JAPhA NS52(4) 457 July/August 2012)

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

2011 Pharmacist's Role in Healthcare Reform

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

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

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

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

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

(JAPhA NS48(4):471 July/August 2008) (Reviewed 2010) (Reviewed 2015)

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

2003, 1992 The Pharmacist's Role in Therapeutic Outcomes

1. APhA affirms that achieving optimal therapeutic outcomes for each patient is a shared responsibility of the health care team.
2. APhA recognizes that a primary responsibility of the pharmacist in achieving optimal therapeutic outcomes is to take an active role in the development and implementation of a therapeutic plan and in the appropriate monitoring of each patient.

(Am Pharm NS32(6):515 June 1992) (JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2007) (Reviewed 2009) (Reviewed 2010)(Reviewed 2011)

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

2013, 1978 Pharmacists Providing Health Care Services

APhA supports the study and development of new methods and procedures whereby pharmacists can increase their ability and expand their opportunities to provide health care services to patients.

(Am Pharm NS18(8):47 July 1978) (Reviewed 2007) (Reviewed 2008) (JAPhA 53(4):366 July/August 2013)



2016 House of Delegates

Report of the Policy Committee

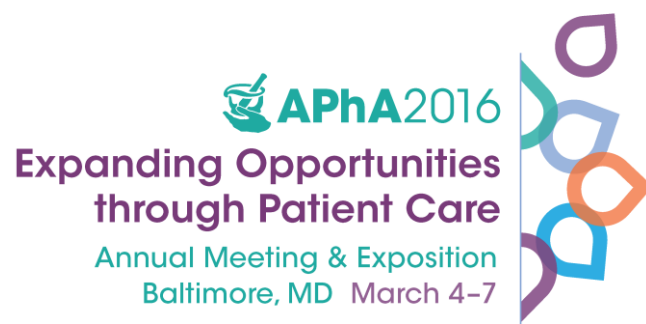
Biologic, Biosimilar, and Interchangeable Biologic Drug Products
Point-of-Care Testing
Medication Optimization Services within the Patient Care Process

Committee Members

Melissa Duke, Chair
Ally Dering-Anderson
Rebecca W. Chater
Karen Nagel Edwards
Elizabeth Johnson
Loren Madden Kirk
Pamela Piotrowski
John Sykora
Benjamin Y. Urick
Krystalyn Weaver

Ex Officio

Theresa Tolle, 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.

2015–2016 APhA Policy Committee Report

Biologic, Biosimilar, and Interchangeable Biologic Drug Products

The committee recommends that the association adopt the following statements:

1. APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.
[Refer to Summary of Discussion Items 1, 2.]
2. APhA urges the Food and Drug Administration (FDA) to expedite the development of standards and pathways to evaluate the interchangeability of biologic products.
[Refer to Summary of Discussion Items 3, 4, 5.]
3. APhA recognizes the Food and Drug Administration's (FDA) Purple Book as the authority on biologic product interchangeability within the United States and discourages development of nonconforming domestic interchangeability lists.
[Refer to Summary of Discussion Items 6, 7, 8.]
4. APhA opposes interchangeable biologic product substitution processes that require authorization, recordkeeping, or reporting beyond generic product substitution processes.
[Refer to Summary of Discussion Items 8, 9.]
5. APhA encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes.
[Refer to Summary of Discussion Items 10, 11.]

Summary of Discussion

1. The committee agreed that the term *biologic products* was the overarching and correct term that encompasses reference and originator biologics, biosimilars, and interchangeable biologics.
2. The committee recognized the need for patient access to biologic drug products and reviewed the APhA **2012, 2007 Biologic Drug Products** policy statement. The committee determined that additional policy was needed to focus on the patient and build on previous policy supporting greater availability of biologic products for patients.
3. The committee recognized the importance of having timely development of standards and pathways that support the evaluation of biologic product interchangeability and access to these products. The committee specifically chose the term *expedite* to promote the development of standards and pathways as a priority for FDA and acknowledged that holdups in the creation of a pathway delay FDA approval of product interchangeability.
4. The committee's use of the term *pathway* aligns with FDA's use of that term to describe the biologic product approval process.
5. The committee discussed the difference between biologics and small molecule drugs based on existing science and their respective development processes (within FDA). The committee determined that current processes used or proposed for the substitution, naming, and labeling of various biologic products may be different from those for small molecule drugs and therefore need to be clarified by regulatory agencies such as FDA.
6. As the term is used within the proposed statement, the committee noted that "authority" is defined as being an accepted source of information or advice.
7. The committee reviewed existing resources in the marketplace for pharmacists to obtain information on biosimilar products and determined FDA's Purple Book was the only

legitimate resource in the United States.¹ The committee agreed that the Purple Book has the best framework to contain necessary information on interchangeable drug products even though it does not, at this time, contain this specific information. The committee noted that once populated, the Purple Book will be the authoritative source for practitioners and decision makers.

8. The committee recognized the importance of sharing clinical information among members of the health care team. After discussing the vision for biologic product interchangeability, the committee determined that the biologic product selection process should mirror the process that practitioners are using for generic product selection. The committee envisioned a process that encompasses the use of FDA's Purple Book to identify interchangeable products and the ability of prescribers to indicate "dispense as written" (DAW) for products for which interchangeability is not desired.
9. In discussing substitution processes, the committee carefully selected the term *opposes* to communicate its strong desire for use of a process that is known by pharmacists and prescribers (i.e., generic substitution processes) and does not place excess burden on pharmacists or other practitioners.
10. The committee reviewed the potential parameters and processes that could be used in determining biosimilarity of products and recognized the importance of having the decision process guided by available scientific data. The committee indicated that such data could include approval tests and clinical trials conducted during evaluation of expanded indications or extrapolation of product indications related to biosimilar or biologic drug products. The committee noted that the term *extrapolation* is specifically used because it is used within the pharmacy industry and by FDA.
11. The committee reviewed the potential action by some states to create their own biosimilar and biologic interchangeability lists. The committee did not want to outright oppose the creation of state-based lists, because a legitimate need for such creation (such as state law prohibiting the citation of a nonstate resource) might exist. However, the committee wanted

developed lists to align with FDA's Purple Book and used the term *discourage* when describing the creation of domestic lists that do not match the Purple Book.

12. The committee discussed concerns about potential safety issues with product naming conventions and the use of suffixes that create confusion among practitioners, patients, and others. As a result, the committee reviewed current policy related to product naming and determined no additional policy was necessary. The committee discerned that current policy allowed for adequate explanation of the need for clear naming conventions related to interchangeability.
13. The committee identified the need for product labeling and information that clearly and easily provide information related to the interchangeability of biologic products. The committee reviewed the varying nomenclature or naming options that exist in the current marketplace and focused on the importance of clear and consistent naming options for pharmacists, student pharmacists, and technicians to understand. The committee reviewed the current process for requiring additional information and determined that requiring more work by FDA may be costly and onerous. The committee determined this topic may be an area for future policy discussion if the Purple Book does not ultimately provide adequate information on product interchangeability.
14. The committee agreed that additional education for pharmacists will be needed upon the approval of an interchangeable biologic pathway. The committee discussed the need for access to biologic products from the perspective of pharmacies and pharmacists, but agreed that at this point in time, not every pharmacist has the necessary knowledge to comfortably dispense these medications because of their complexity and unclear substitution processes.
15. The committee reviewed current policy on pharmacovigilance and risk evaluation mitigation strategies and recognized the need to address patient safety with regard to biologic products. The committee determined no additional policy was necessary on these two topics because the current APhA policy is broad enough to encompass biologic products as needed.

Reference

1. U.S. Food and Drug Administration. *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity of Interchangeability Evaluations* [Purple Book]. Washington, DC: U.S. Food and Drug Administration; 2014.

Biologic, Biosimilar, and Interchangeable Biologic Drug Products
Background Paper Prepared for the 2015–2016 APhA Policy Committee

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Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2015–2016 Policy Committee to recommend policy to the APhA House of Delegates. The Board's guidance on this topic included, but was not limited to, product interchangeability, product naming conventions, clarification on drug development and approval, and the pharmacist's role regarding product substitution.

Summary of Key Concepts

- Before enactment of the Patient Protection and Affordable Care Act (PPACA), a legal pathway for manufacturers to produce versions of previously approved biologic products did not exist. Since then, the Biologics Price Competition and Innovation Act (BPCIA) has created a legal pathway for this process and relies on regulation by the Food and Drug Administration (FDA) to determine the specific pathway for approval of products.
- Biosimilars are not simply generic biologics as Differences exist between scientific construction of the products themselves and approval pathways from a regulatory perspective.
- Small-molecule drugs differ from biologics in size, structure, manufacturing processes, and immunogenicity, leading to difficulty in modeling exact creation and approval processes from brand and generic processes.
- FDA has outlined a stepwise approach to obtaining approval for biosimilarity that involves studies and data of structure, function, animal toxicity, pharmacokinetics (PK) and pharmacodynamics (PD), immunogenicity, and clinical safety and efficacy. A difference with biosimilars regarding the PK and PD aspects of the end product will be a focus of final product information.
- Interchangeability remains an issue in the pharmacy profession because current federal law does not allow pharmacists to substitute these products automatically and because many states are adding varying rules or statutes regarding permission for a pharmacist to substitute these products.
- The naming of biosimilar products is still problematic despite guidance documents provided by the World Health Organization (WHO) and FDA.
- Product substitution by pharmacists is an area of further evaluation. Although FDA has created the Purple Book for assistance with biosimilar product substitution, many states are passing state-specific laws. These laws outline multiple aspects of the substitution process, including communication with providers and recordkeeping requirements.

Introduction

For most of the past two decades, some biological products have had market exclusivity in the United States. Biosimilars, approved through their own FDA pathway, introduce competition into the marketplace for biological medications. Such competition should result in more competitive (i.e., lower) prices and provide an incentive for biological product manufacturers to innovate and discover newer, more effective products.² Before passage of the PPACA in 2010, a legal pathway to allow other manufacturers to produce versions of already-licensed biological products did not exist. The PPACA

included the BPCIA, which created a legal pathway for the development of biosimilars and charged FDA with developing the pathway for approval of biosimilar products.³ Table 1 describes the types of biological products (from a regulatory perspective) that can be approved by FDA. FDA licenses novel biologics through the 351(a) pathway (found at section 351[a] of the Public Health Service [PHS] Act). For novel biologics, sponsors must demonstrate safety and efficacy for market authorization. In contrast, biosimilars are approved under the 351(k) pathway. Under section 351(k) of the PHS Act, sponsors must demonstrate that the biosimilar is “highly similar” to a reference product that was approved through section 351(a) of the PHS Act. If a biologic product manufacturer decides to produce another version of an already-approved biologic product, the decision to seek approval through the 351(a) or 351(k) pathway will depend on the company’s business strategy.

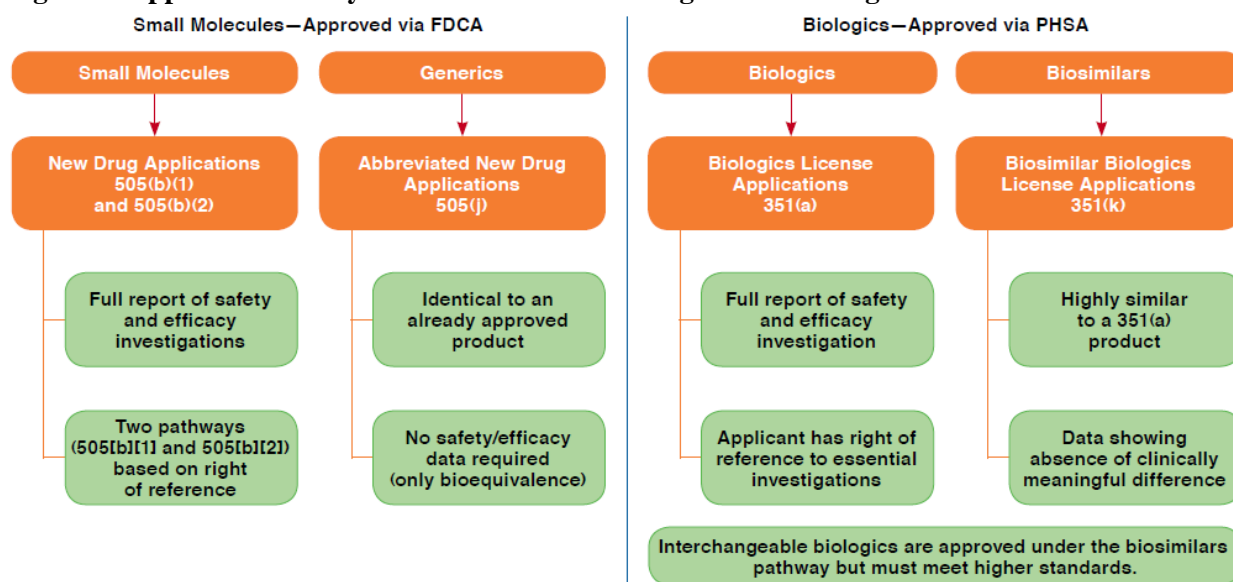
Table 1. Regulatory Types of Biological Products

Aspect	351(a) Originator	351(k) Biosimilar	351(k) Interchangeable biosimilar	351(a) Nonoriginator biologic
Description	First-to market biologic molecule; will likely be the reference product	“Highly similar” to reference product; approved via biosimilars pathway	A biosimilar that meets additional standards so that it can be substituted for the reference product without permission from prescriber	another brand name of an already approved biologic
Depth of data submitted to FDA	Standard data package of efficacy and safety	Abbreviated data package for comparability	Abbreviated data package for comparability; more information on switching	Standard data package of efficacy and safety
Compared to originator?	NA	Yes	Yes	Not necessary (yes or no)
Implications		Biosimilar pricing; explicit regulatory oversight on comparison with reference product; possible product substitution by pharmacist (for interchangeable biosimilars)		Different pricing structure and substitution issues

FDA = U.S. Food and Drug Administration; NA = not applicable. (Adapted from Lucio et al, 2013)³

Akin to generic small-molecule drugs, biosimilars have the potential to drive down prices of biological products through competition. Patients can realize significant cost savings when pharmacists, as medically appropriate for each patient, substitute a less expensive biosimilar with an equivalent safety and efficacy profile for the branded biologic. However, significant differences exist between biosimilars and generics that add a layer of complexity to the issue of a pharmacist’s product substitution of biological medications. Generic small-molecule drugs are approved through the Abbreviated New Drug Application pathway, where the standard of approval is whether the generic drug is bioequivalent to the branded product. Thus, FDA does not require additional data regarding safety and efficacy from the generic product manufacturer. However, the bioequivalence standard alone is not sufficient in regard to allowing different versions of a biological product to come to market. Therefore, a new standard has been established to explicitly compare biological medications—biosimilarity. Biosimilars are not simply generic biologics, and the differences in scientific principles of construction and approval processes must be carefully considered in regulatory and practice contexts. The standards of bioequivalence and biosimilarity are juxtaposed in Figure 1, which compares the approval pathways for drugs and biologics. This background paper reviews the differences between biologics and small-molecule drugs and discusses how these differences translate into a distinct manner in approving for market and regulating biosimilar products. This distinction has a clear effect in the way pharmacists will practice.

Figure 1. Approval Pathways for Small-Molecule Drugs versus Biologics



Note: For historical reasons, a few biological products are currently approved under the FDCA. However, under the BPCI Act, all biological products will be approved under the PHSA beginning in 2020.

BPCI Act=Biologics Price Competition and Innovation Act; FDCA=Food, Drug, and Cosmetic Act; PHSA=Public Health Service Act.

Source: (Li et al., 2015)⁵

How do Biologics Differ from Small-Molecule Drugs?

According to the U.S. Code of Federal Regulations, Section 600.3, the technical definition of a biologic is: “any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.”⁶ These are medicinal protein products derived and produced from living organisms, typically bacterial, fungal, or mammalian cells, whereas small-molecule chemical drugs are synthesized through chemical reactions within a controlled environment. Because biological medications are manufactured using living systems, they are typically far more complex than small-molecule drugs, in size, structure, manufacturing, characterization, stability, and immunogenicity (see Table 2).⁷

Table 2. Differences between Small-Molecule Drugs and Biologics

Characteristic	Small-molecule drugs	Biologics
Size	Small; low molecular weight	Large; high molecular weight
Structure	Simple, well-defined	Complex, heterogeneous
Manufacturing	Reproducible chemical reactions in which identical copies of the active ingredient can be made	Creation through living systems; impossible to fully copy active ingredient
Characterization	Completely characterized	Impossible to fully characterize molecular composition
Stability	Stable	Unstable; sensitive to external conditions
Immunogenicity	Mostly nonimmunogenic	Immunogenic

Adapted from (Declerck 2012)⁷

In particular, the manufacturing of biological medications differs vastly from that of small-molecule drugs.⁸ As protein products with a clear amino acid sequence, biologics are produced by a target DNA

(deoxyribonucleic acid) sequence being transferred into a target host cell through a vector such as a plasmid or a viral vector. After a manufacturer determines that this transfected host cell can effectively express the protein, the cells are cultured and expanded within large bioreactors under specific, controlled conditions (e.g., growth media, temperature, etc.). When the cells have produced a sufficient amount of the biologic, it must be recovered through a combination of filtration and centrifugation, and finally purified through chromatography. The structure, function, and purity of the final bulk drug must then be fully characterized using analytical techniques. Because of the inherent heterogeneity of the process, the final biological product will contain a myriad of different components, such as an active biologic with different post-translational modifications to the protein and impurities within the bulk product. However, the pattern of these components should be consistent from lot to lot and must meet specific quality standards as currently outlined by international standards discussed in many FDA guidance documents.⁹

The composition of the resulting finalized biological product is highly dependent on the manufacturing process, and changes to the process may result in a different product (e.g., with post-translational modifications or impurities), which may or may not be clinically meaningful in terms of efficacy and safety (including immunogenicity). When biological product manufacturers are considering a manufacturing change, they are subject to current FDA regulations that explain which data need to be submitted to FDA to demonstrate that the potential changes will not result in any “adverse impact on the quality, safety, and efficacy of the drug product.”¹⁰ This process has been successfully applied to many biological products currently available in the United States. For example, rituximab, etanercept, and darbepoetin have undergone manufacturing process changes. Despite some differences in post-translational modifications of the product, no clinical consequences were expected and thus FDA deemed no labeling changes or further clinical studies necessary.¹¹

The aforementioned process is used when a manufacturer of an existing biological product desires a manufacturing change, mostly as a result of improvements in technology or increases to production scale or in response to fluctuations in the supply of raw materials. Such changes are common and can occur infrequently or upward of 30 times within a biologic’s life cycle.¹² However, when another biological product manufacturer (manufacturer B) wishes to produce a version of an existing product from an originator manufacturer (manufacturer A), the manufacturing process is likely to differ significantly from the originator manufacturer’s process, because of proprietary processes and trade secrets.

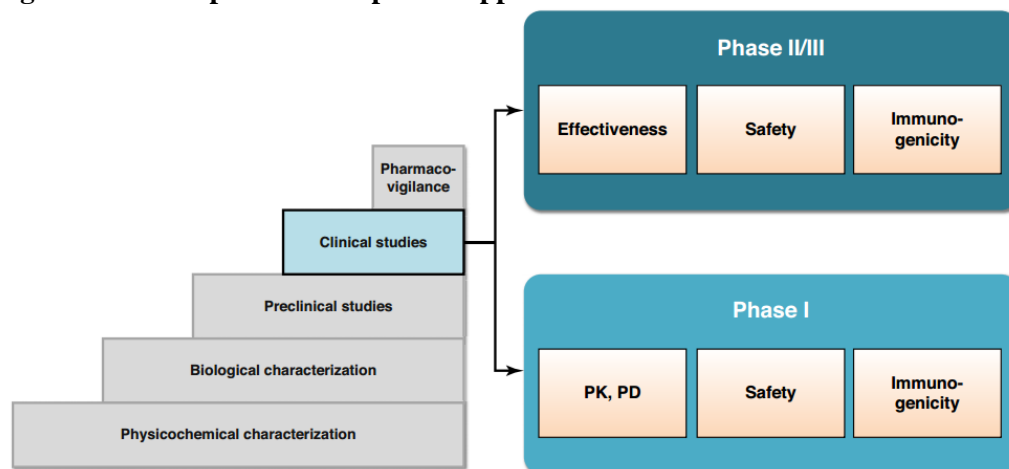
Accordingly, the concerns regarding whether the final biological product is comparable from manufacturer A to manufacturer B also include whether differences would be likely to result in clinically meaningful effects. So unlike sponsors of generic drugs, who must demonstrate only *bioequivalence*, sponsors of candidate versions must show *biosimilarity*, meaning that the products are “highly similar with no clinically meaningful differences” (notwithstanding minor differences in inactive components). At the same time, the pathway for approval must be significantly abbreviated so that development costs for biosimilars will be lower than for novel biologics. To evaluate the safety and efficacy of biosimilars before approval, FDA has developed the 351(k) pathway noted earlier.

FDA Guidance for the Approval of Biosimilars

The approval of a biosimilar product is a scientifically based, comprehensive comparability exercise. The purpose for demonstrating biosimilarity is *not* to demonstrate that the biologic is safe and effective per se; the reference biologic’s manufacturer already demonstrated this in the initial 351(a) application to FDA. Rather, as discussed earlier, sponsors must demonstrate that the biosimilar does not have any “clinically meaningful differences,”—in essence, that it produces patient results similar to those of the reference product. Accordingly, smaller-scale studies and extrapolation are used to determine biosimilarity. FDA has outlined a stepwise approach, which includes a comparison of the candidate biosimilar to the reference biologic in the domains of structure, function, animal toxicity studies, human PK and PD

studies, clinical immunogenicity, and other clinical studies to compare efficacy and safety.¹³ As depicted in Figure 2, this stepwise approach compares the biosimilar to the reference biologic in physiochemical and biological characteristics (through in vitro methods) and bioequivalence (all biosimilars must be bioequivalent to the reference product), safety, and efficacy through human clinical trials.

Figure 2. The Stepwise Development Approach for a Biosimilar



PK = pharmacokinetics; PD = pharmacodynamics. Adapted from (Li et al. 2015)¹⁴

Table 3 outlines the elements within each step to address comparability of the candidate biosimilar to the reference biologic within each domain. In each of the clinical studies, the endpoint chosen for comparison between the reference biologic and the biosimilar will be the most sensitive—where differences in the endpoint would translate into clinical differences between the products. The data package for biosimilars represents a paradigm shift from the way clinicians are accustomed to making therapeutic decisions. For biosimilars, the data package will focus more on the preclinical analyses of structure and function with robust evidence for PK and PD and less on comparative clinical studies for efficacy. Accordingly, FDA may choose to use a clinical study evaluating one indication and extrapolate the approval of the biosimilar to include some or all of the reference product’s FDA-approved indications. The extrapolation decision is based on many factors such as the similarity of the mechanism of action across extrapolated indications, the target receptors involved, the immunogenicity profile between extrapolated populations, and the extent of the preclinical data.¹⁵

Table 3. Stepwise Approach toward Demonstrating Biosimilarity

Step	Role	Element
Structure	Serves as the foundation for biosimilar development	<ul style="list-style-type: none"> Determine quality attributes in terms of amino acid sequence, higher-order structures, post-translational modifications (e.g., glycosylation, PEGylation), etc. Analyze lot-to-lot variability.
Function	Serves as the foundation for biosimilar development	<ul style="list-style-type: none"> Determine quality attributes in terms of pharmacologic activity through in vitro or in vivo experiments. Determine specific assays based on the molecule’s mechanism of action.

Animal toxicity	Useful when unresolved questions exist about the safety of the candidate biosimilar based on studies of structure and function	<ul style="list-style-type: none"> • Comparative animal toxicology design depends on the unresolved questions identified through comparability studies of structure and function.
Pharmacokinetics (PK) and pharmacodynamics (PD)	Fundamental for demonstrating biosimilarity	<ul style="list-style-type: none"> • Assess bioequivalence in a sensitive population (PK). • Use a sensitive PD endpoint that is predictive of clinical outcomes. • Use crossover and parallel designs.
Immunogenicity	Evaluation of potential differences in incidence and severity of immune responses	<ul style="list-style-type: none"> • Endpoints include antibody formation (binding, neutralizing), cytokine levels, etc. • Comparative parallel study can be used. • Analysis is done mainly within the PK and PD and the efficacy and safety studies.
Clinical safety and efficacy	Required to answer unresolved questions based on PK and PD studies to demonstrate neither decreased nor increased activity (sometimes not necessary if there is a robust PD marker)	<ul style="list-style-type: none"> • Noninferiority and equivalence study designs are used. • Specific clinical trial design will depend on remaining residual questions. • Specific endpoint and population will depend on discussions with opinion leaders and with FDA. • FDA may be allowed to extrapolate to other FDA-approved indications.

FDA considers the totality of the evidence when reviewing candidate biosimilars for approval. For example, if the studies of structure and function with the biosimilar are highly comparable to the reference product, then the product has very high confidence and low residual uncertainty, requiring only more targeted clinical studies to confirm biosimilarity. Likewise, if higher uncertainty exists after review of the data for structure and function, FDA may require more clinical studies, such as comparative PK and PD and safety and efficacy studies, before approving the candidate biosimilar.¹⁶ In cases involving an excellent PD marker that correlates well with clinical efficacy, the regulatory authority may not require comparative studies of efficacy and safety for approval as a biosimilar.¹⁷ Immunogenicity assessments will be incorporated into the human clinical studies and are required to be comparable in incidence and severity of immune-related effects.

Although FDA has not yet created a pathway for determinations of interchangeability, biosimilars demonstrating that switching between the reference product and the biosimilar in the same patient creates no immunogenic and other safety concerns may be designated *interchangeable* with the reference product. The implications of being an interchangeable biosimilar are discussed later.

Because clinical studies for market approval are not designed to detect rare but serious adverse events, long-term pharmacovigilance studies are also important for ensuring that a biosimilar is equivalent to the reference biologic in safety events. One of the main goals with ongoing pharmacovigilance programs is assessing whether serious adverse events (should they arise) are product specific (e.g., a result of the

vehicle or other factors of the final biological product) or molecule specific (e.g., a result of the molecule's pharmacologic properties).

Unresolved Policy Issues

The FDA has finalized its guidance documents for industry and has approved the first biosimilar in the United States. However, a number of issues have not been resolved at the national level: interchangeability, biosimilar naming, and Medicare and Medicaid reimbursement.

Interchangeability

Provisions within the BPCIA allow for a biosimilar to be designated *interchangeable* if it meets additional standards beyond biosimilarity. An interchangeable product is one that “can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.”¹³ Currently, FDA has not released guidance regarding what data are required from a biosimilar product manufacturer to meet the definition of interchangeability. However, statisticians have proposed various study designs that incorporate switching between the biosimilar and reference product.¹⁸

The implications for the availability of an interchangeable biosimilar product are clear: the BPCIA indicates that interchangeable biosimilars “may be substituted for the reference product without the intervention of the prescribing healthcare provider.”¹³ The fact that the BPCIA does not give pharmacists the authority to make substitutions is important; pharmacists practice under the authority given to them by individual state pharmacy practice laws. However, because FDA has not yet released interchangeability standards and because current guidance documents indicate that FDA anticipates that obtaining an interchangeability designation at the time of first approval will be “difficult,” interchangeable biosimilars are unlikely to be available in the near future.¹⁴ Further, if sponsors of biosimilars approved before the development of an interchangeability pathway want to switch their product designation to interchangeable, they will almost certainly have to submit additional clinical and other supporting data (note: a product can be a biosimilar or an interchangeable biosimilar, but not both).

Biosimilar Naming

The nonproprietary naming of biosimilars has been another area of contention since the passage of the BPCIA. The issue has two sides: whether the biosimilar should share the reference product's exact nonproprietary name, or whether biosimilars should have distinct names. Those who advocate for the same name cite the experience with generic drugs that the same name facilitates substitution and may improve public and prescriber acceptance and uptake of biosimilars. In a recent survey of pharmacists who are members of the Academy of Managed Care Pharmacy, American Society of Health-System Pharmacists, or APhA, respondents indicated greater confidence in substituting an interchangeable biosimilar for the reference product if both products shared the same name.¹⁹ Advocates for different names state that such names are necessary to facilitate pharmacovigilance programs. Currently, both active and passive adverse event surveillance programs identify products through their nonproprietary names. Limitations have been identified where having the same nonproprietary name may lead to false safety signals. In one study, the authors identified an underrepresentation of reports that were specifically attributable to a generic enoxaparin manufacturer when evaluating spontaneous reports to the FDA MedWatch program, despite a robust market share of generic enoxaparin products.²⁰ Proponents of a shared nonproprietary name counter the pharmacovigilance argument by suggesting that deficiencies in

reporting systems should be addressed by improving those systems rather than proceeding through the biosimilars naming framework.

Recently, the World Health Organization released its proposal to address biosimilar naming.²¹ It suggests adding a voluntary, four-character *biological qualifier* to the end of the biologic's traditional international nonproprietary name (INN), not as part of the INN, but as an "additional and independent element used in conjunction with the INN." This biological qualifier would be devoid of meaning, but it would allow practitioners to trace the product back to a specific manufacturer for pharmacovigilance purposes.

In August 2015, FDA released its draft guidance on biosimilar naming.²² Its proposed framework closely matches the concepts outlined by the WHO. In the draft guidance, FDA proposes adding a four-letter suffix to the end of a biosimilar's nonproprietary name that is unique and nonpromotional. FDA has requested feedback on whether four-letter suffixes should be random (e.g., devoid of meaning, thereby mirroring the WHO's proposal) or meaningful (e.g., keyed to the manufacturer's name) like the placeholder name given to the first FDA-approved biosimilar, filgrastim-sndz. FDA cites avoiding inadvertent biosimilar substitution and facilitating pharmacovigilance as reasons for choosing this naming convention. It has not yet decided whether interchangeable biosimilars will have a suffix or whether they will share the same name as the reference product and has requested stakeholder input on the issue.

Biosimilar Reimbursement—Centers for Medicare and Medicaid Services

According to the BPCIA, Medicare will reimburse the cost of a biosimilar product at 100% of the biosimilar's average sale price (ASP) plus 6% of the reference product's ASP.²⁴ This approach was designed to provide a financial incentive (e.g., maintain a profitable margin) to health care practices to use the lower-price product. Recently, the Centers for Medicare and Medicaid Services has clarified its payment policy for biosimilars, stating that it intends to group all biosimilars together (including those designated as interchangeable) separately from the reference product within a single Healthcare Common Procedure Coding System (HCPCS, or J-code) for the reimbursement calculation.²³ Many believe that this policy decision will have negative effects on biosimilar pharmacovigilance, because HCPCS codes within claims data are routinely used to identify specific products for pharmacovigilance (active surveillance) and research purposes (e.g., comparative effectiveness). Grouping biosimilars into a common HCPCS code will facilitate claims administration but will diminish researchers' capability to correctly attribute a safety signal to a particular manufacturer.

The reimbursement model from Centers for Medicare and Medicaid Services has meaningful implications for the remaining members of the U.S. population, because they often serve as reimbursement models for private payers. However, the way that private payers will approach reimbursement for biosimilars is unknown. One possibility will be driving use toward one specific product, but the concern is that the specific product will not always have the least costly acquisition price because of site-specific contracting. Any reimbursement policy should recognize that different providers will have different acquisition prices for each biological product.

Issues Related to Pharmacy Practice

Operational Challenges

Because biosimilars are a novel regulatory type of medication product within the United States, pharmacists will face specific operational challenges. These challenges generally fall within the broad categories of formulary analysis, order management and information systems, inventory management, financial analysis, and education.²⁴ Table 4 summarizes key challenges within each domain.

Table 4. Key Operational Challenges with Biosimilars

Domain	Element
Formulary analysis	<ul style="list-style-type: none"> • Product approval pathway and data package • Appropriate indications (on label and off label) for use • Extrapolation considerations • Therapeutic interchange +/- guided use policies • Transitions of care • Payer mix
Order management and information systems	<ul style="list-style-type: none"> • Differentiation of biosimilar and reference product in electronic systems to prevent inadvertent substitution and facilitate pharmacovigilance • Ordering of sets, protocols, and MARs • Medication reconciliation
Inventory management	<ul style="list-style-type: none"> • Buyer's need for adequate information (NDC code, etc.). • Confirmation of whether both biosimilar and reference are in stock • Maintenance of product storage and handling conditions
Financial analysis	<ul style="list-style-type: none"> • Pricing information comparison (base, contract, reimbursement, margin) • Staff management time • Patient assistance and out-of-pocket expenses • Determination of financial impact
Education	<ul style="list-style-type: none"> • Drug information and education to all providers (clinical data, policies, etc.) • Patient education materials

MARS = medication administration records; NDC = National Drug Code. Adapted from (Lucio et al., 2013)²⁴

Product Substitution by Pharmacist

For the greatest effect of biosimilars in reducing (or moderating) health care expenditures, a pharmacist should be able to act independently of the prescriber (using professional autonomy and judgment) to substitute the least expensive, pharmaceutically equivalent medication product for the drug prescribed. The success of generic medications in reducing health care costs has been well established, and much of that success can be attributed to the pharmacist's ability to autonomously substitute these products for the branded drug. The goal is the same for biosimilars, but additional considerations exist for pharmacists when considering whether they should substitute and whether they have received sufficient authority by their respective state to do so.

The first challenge with biosimilar substitution is the standard by which a substitution can be made. For small-molecule drugs, those generally meeting a bioequivalence standard set by FDA are appropriate for substitution. By definition, a biosimilar must be bioequivalent to the reference product, but additional requirements given by FDA include studies of structure and function; human pharmacodynamics studies; and clinical studies demonstrating equivalence to the reference product in safety, efficacy, and immunogenicity endpoints.

As previously mentioned, FDA has defined an interchangeable biosimilar as a product that would be appropriate for a pharmacist to substitute for the reference product because there is no clinical risk in switching between the interchangeable biosimilar and the reference product. FDA has published the Purple Book with a list of all biological products (including biosimilars) and ratings of whether the products are interchangeable with another product.¹ Akin to their use of the Orange Book for small-

molecule drugs, pharmacists are expected to be able to make substitution decisions based on this publication.²⁵ Switching between a non-interchangeable biosimilar and the reference product is not generally recommended for patients because of concerns regarding immunogenicity. Therefore, if a patient begins treatment with the non-interchangeable biosimilar or the reference product, he or she should continue treatment with the product that was first administered. This approach may present challenges with continuity of care and transitions of care when patients transfer from one setting (e.g., the community) to another (e.g., the hospital or long-term care).

The second challenge with biosimilar substitution is whether state pharmacy practice laws provide a pharmacist with sufficient authority to substitute biological products. Although substitution laws are currently in place for generic drugs, whether the language is sufficiently translatable to biological medications is unclear. Further, some state laws specifically reference the Orange Book as the list of pharmaceutical products deemed appropriate for substitution.²⁴ Some states have been proactively passing laws to specifically address biosimilar substitution. Although some have argued that these are “biosimilar anti-substitution laws,”²⁶ the enacted laws generally follow the same framework for generic drugs by mentioning the criteria for product substitution; having a “dispense as written” provision; requiring communication about substitution to the prescriber or patient; and requiring recordkeeping. Because of the concerns noted earlier regarding biosimilar pharmacovigilance, state laws typically require more prescriber and patient communication and recordkeeping. Table 5 contains examples of these elements from states that have passed biosimilar substitution laws.

Table 5. Examples of State-Level Biosimilar Substitution Laws

State	DAW provision	Product’s criteria for substitution and interchangeability	Prescriber and patient communication	Recordkeeping
Delaware ²⁷	Yes	FDA designated interchangeable product or therapeutic equivalent.	Inform patient; inform prescriber in 10 days.	Same as generic law
Florida ²⁸	Yes	FDA determined interchangeability.	Inform patient same as generic; notify by EMR documentation if practicing in an institution.	2 years
Virginia ²⁹	Yes	FDA determined interchangeability.	Inform patient of cost; inform prescriber within 5 days.	2 years
Massachusetts ³⁰	Yes	FDA determined interchangeability.	Inform patient and prescriber (no timeline).	1 year

DAW = dispense as written; FDA = U.S. Food and Drug Administration; EMR = electronic medical record.

As can be seen from table 5, these state laws provide explicit authority for a pharmacist to substitute an interchangeable biosimilar for the reference product, with stipulations on communication and recordkeeping. Because each state is different in its approach to generic substitution, a similar model could be used for biosimilar substitution on a state-by-state basis, with each state deciding the best approach for communication and recordkeeping. The involvement of practicing pharmacists in crafting the language for such laws is important.

Conclusion

The introduction of biosimilars into the U.S. marketplace is an opportunity to moderate costs related to traditionally expensive medications. Experience in Europe indicates that these products are therapeutically equivalent to their reference products and confer moderate savings. Some policy issues remain unresolved in the United States, such as naming, interchangeability, and reimbursement. Additionally, pharmacists will have responsibility for substituting biosimilars and incorporating them into the medication use process within their practice. Further, survey studies indicate that more education is needed about biosimilars.^{19, 31} Thus, pharmacists are also likely to take the lead in educating other health care providers and patients regarding biosimilars within their respective practices.

References

1. U.S. Food and Drug Administration. *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* [Purple Book]. Washington, DC: U.S. Food and Drug Administration; 2014. Available at: www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm.
2. Blackstone EA, Joseph PF. The economics of biosimilars. *Am Health Drug Benefits*. 2013;6(8):469–78.
3. Patient Protection and Affordable Care Act, Pub. L. 111–148, title VII, sections 7001–7003 (2010).
4. Lucio SD, Stevenson JG, Hoffman JM. Biosimilars: implications for health-system pharmacists. *Am J Health Syst Pharm*. 2013;70(22):2004–17.
5. Li EC, Ramanan S, Green L. Pharmacist substitution of biological products: Issues and considerations. *J Manag Care Spec Pharm*. 2015;21(7):532–39.
6. U.S. Code of Federal Regulations, Title 21, Subchapter F—Biologics. Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=600.3.
7. Declerck PJ. Biologicals and biosimilars: a review of the science and its implications. *GaBI Journal*. 2012;1(1):13–6.
8. Mellstedt H, Niederwieser D, Ludwig H. The challenge of biosimilars. *Ann Oncol*. 2008;19:411–9.
9. U.S. Food and Drug Administration. International conference on harmonisation—quality. Available at: www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm. Accessed October 5, 2015.
10. U.S. Food and Drug Administration. Guidance for Industry: Q5E comparability of biotechnological/biological products subject to changes in their manufacturing process. Available at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073476.pdf. Accessed August 2015.
11. Schiestl M, Stangler T, Torella C, et al. Acceptable changes in quality attributes of glycosylated biopharmaceuticals. *Nat Biotechnol*. 2011;29:310–12.
12. Schneider CK. Biosimilars in rheumatology: the wind of change. *Ann Rheum Dis*. 2013;72(3):315–18.
13. U.S. Food and Drug Administration. Guidance for industry: scientific considerations in demonstrating biosimilarity to a reference product. Available at: www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.
14. Li EC, Abbas R, Jacobs IA, Yin D. Considerations in the early development of biosimilar products. *Drug Discov Today*. 2015;20(Suppl 2):1–9.
15. Weise M, Kurki P, Wolff-Holz E, et al. Biosimilars: the science of extrapolation. *Blood*. 2014;124(22):3191–16.
16. U.S. Food and Drug Administration. Guidance for industry: clinical pharmacology data to support a demonstration of biosimilarity to a reference product—draft guidance. Available at:

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM397017.pdf. Accessed October 5, 2015.

17. Heinemann L, Hompesch M. Biosimilar insulins: how similar is similar? *J Diabetes Sci Technol*. 2011;5(3):741–54.
18. Chow SC, Yang LY, Starr A, Chiu ST. Statistical methods for assessing interchangeability of biosimilars. *Stat Med*. 2013;32(3):442–48.
19. Fernandez-Lopez S, Kazzaz D, Bashir M, McLaughlin T. Assessment of pharmacists' views on biosimilar naming conventions. *J Manag Care Spec Pharm*. 2015;21(3):188–95.
20. Grampp G, Bonafede M, Felix T, et al. Active and passive surveillance of enoxaparin generics: a case study relevant to biosimilars. *Expert Opin Drug Saf*. 2015; 14(3):349–60.
21. World Health Organization. Biological qualifier: an INN proposal. Revised draft July 2014. Available at: www.who.int/medicines/services/inn/bq_innproposal201407.pdf. Accessed August 29, 2015.
22. U.S. Food and Drug Administration. Guidance for Industry: nonproprietary naming of biological products Guidance for Industry—draft guidance. Available at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf. Accessed August 29, 2015.
23. Centers for Medicare and Medicaid Services. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to part B for CY 2016. *Fed Regist*. 2015;80:41685. Available at: <https://www.federalregister.gov/articles/2015/07/15/2015-16875/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions#h-206>. Accessed August 29, 2015.
24. Lucio SD, Stevenson JG, Hoffman JM. Biosimilars: implications for health-system pharmacists. *Am J Health Syst Pharm*. 2013;70(22):2004–1.
25. U.S. Food and Drug Administration. *Approved Drug Products with Therapeutic Equivalence Evaluations* [Orange Book]. Washington, DC: U.S. Food and Drug Administration; 2015.
26. Sarpatwari A, Avorn J, Kesselheim AS. Progress and hurdles for follow-on biologics. *N Engl J Med*. 2015;372(25):2380–82.
27. State of Delaware, Delaware Administrative Code, Title 24- Chapter 25. Pharmacy. Available at: <http://tudelcode.delaware.gov/title24/c025/sc06/index.shtml>.
28. Florida House of Representatives, 2013 Legislature, HB 365. Available at: www.flsenate.gov/Session/Bill/2013/0365/BillText/er/PDF.
29. Virginia Acts of Assembly, 2013 Session, H 1422. Available at: <https://leg1.state.va.us/cgi-bin/legp504.exe?131+ful+CHAP0412>.
30. Cerundolo P, Heuer T, Massachusetts Enacts New Biosimilars Substitution Law, FoleyHoag Publications Website. Available at: www.foleyhoag.com/publications/alerts-and-updates/2014/june/massachusetts-enacts-new-biosimilars-substitution-law. June 25, 2014. Accessed August 29, 2015.
31. Zelenetz AD, Ahmed I, Braud EL, et al. NCCN Biosimilars white paper: regulatory, scientific, and patient safety perspectives. *J Natl Compr Canc Netw*. 2011;9(Suppl 4):S1–22.

Relevant APhA Policies

2012, 2007 *Biologic Drug Products*

1. APhA encourages the development of safe, effective, and affordable therapeutically equivalent generic/biosimilar versions of biologic drug products, including clinical trials that assess safety.
2. APhA encourages the FDA to develop a scientifically based process to approve therapeutically equivalent generic/biosimilar versions of biologic drug products.
3. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.
4. APhA should initiate educational programs for pharmacists and other health care professionals concerning the determination of therapeutic equivalence of generic/biosimilar versions of biologic drug products.

(JAPhA NS45(5):580 September-October 2007))(JAPhA NS52(4) 458 July/August 2012)

1991 *Biotechnology*

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

(Am Pharm NS31(6):29 June 1991)(Reviewed 2004)(Reviewed 2007)(Reviewed 2010)

2005, 1988 *Pharmaceutical Biotechnology Products*

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

(Am Pharm NS28(6):394 June 1988) (JAPhA NS45(5):559 September/October 2005)(Reviewed 2006)
(Reviewed 2007) (Reviewed 2010)

2015–2016 APhA Policy Committee Report

Point-of-Care Testing

The committee recommends that the association adopt the following statements:

1. APhA recognizes the value of pharmacist-provided point-of-care testing and related clinical services and promotes the provision of these tests and services in accordance with the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process.
[Refer to Summary of Discussion Items 3, 4, 5.]
2. APhA supports laws, regulations, and policies that enable pharmacists to order, perform, interpret, and act on the results of point-of-care testing consistent with their role in team-based care.
[Refer to Summary of Discussion Items 3, 4, 5, 6, 7, 8, 9, 10.]
3. APhA opposes laws, regulations, and policies that create barriers to Clinical Laboratory Improvement Amendments (CLIA)–waived tests administered and interpreted by pharmacists.
[Refer to Summary of Discussion Items 11, 12.]
4. APhA encourages use of education programs and resources to facilitate practice implementation of point-of-care testing and related clinical services.
[Refer to Summary of Discussion Items 13, 14.]
5. APhA supports patients taking an active role in the management of their health, including the ability to request and obtain pharmacist-provided point-of-care tests and related clinical services.
[Refer to Summary of Discussion Item 15.]
6. APhA supports access to, coverage of, and payment for both point-of-care tests and related clinical services provided by pharmacists.
[Refer to Summary of Discussion Items 16, 17.]

Summary of Discussion

1. Point-of-care testing (POCT) encompasses “performing a robust diagnostic test outside of a laboratory at or near the patient that provides a reliable result rapidly to aid in disease screening, diagnosis, and/or patient monitoring.”¹ Examples of POCT include, but are not limited to, obtaining a serum creatinine level to gauge renal function; ordering a hemoglobin A1C level to determine blood glucose control; and performing rapid diagnostic testing (e.g., testing for Group A *Streptococcus*, influenza, respiratory syncytial virus, hepatitis C, human immunodeficiency virus [HIV], and so on) for the confirmation of a specific disease.²
2. To ensure the accuracy, quality, and reliability of laboratory test results, the Clinical Laboratory Improvement Amendments (CLIA) were passed in 1988 and finalized in 1992. CLIA requires laboratories to meet standardized certification parameters in order to perform tests on human specimens. However, if a laboratory test could be performed with a “minimal level of complexity and low risk of erroneous results,” an exception could be granted to perform this testing in a nonlaboratory setting (e.g., pharmacy, clinic, or other nonlaboratory setting)—a CLIA-waived test.^{2,3} The committee acknowledged variability in state oversight and requirements related to CLIA-waived testing and therefore developed a proposed policy statement specifically addressing that issue.
3. The committee agreed that POCT provided by a pharmacist is also accompanied by clinical services, including counseling on results. The committee reviewed how patient information is used collaboratively with patients and other health care providers and determined that use of POCT in the policy statements includes the conducting of the test, use of the information within the patient care process, and appropriate follow-up.
4. The committee reviewed the following language in the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process document related to team-based care: “In addition, at the core of the process, pharmacists continually collaborate, document, and communicate with physicians, other pharmacists, and other health care professionals in the provision of safe, effective, and coordinated care.” Drawing on the guidance in the JCPP

Pharmacists' Patient Care Process, the committee determined that following the Pharmacists' Patient Care Process as a standard of care would avoid the potential for unnecessary duplicate tests and would optimize the use of pharmacist-based test results by all members of the health care team.

5. JCPP was established in 1977 and serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners and invited liaison members. JCPP members are the Academy of Managed Care Pharmacy, Accreditation Council for Pharmacy Education, American Association of Colleges of Pharmacy, American College of Apothecaries, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Alliance of State Pharmacy Associations, National Association of Boards of Pharmacy, and National Community Pharmacists Association.
6. The committee recognized that state laws, regulations, and policies are not consistent across the nation and that some restrict pharmacists' ability to perform point-of-care testing services, with no clinical justification for such restrictions. The committee acknowledged the importance of calling for empowering language that facilitates pharmacists' ability to provide these services.
7. The committee discussed key elements related to team-based care, collaboration, coordination, and communication and their effect on pharmacists' ability to meet expectations as team members. The committee agreed that the need to report back to providers is covered by use of the term *team-based care*. The committee discussed the potential for duplication of testing and determined that effective involvement within a team-based care model would reduce unnecessary services.
8. The committee reviewed the National Association of Boards of Pharmacy (NABP) Model Practice Act and identified gaps in point-of-care testing language. The committee did not draft specific policy related to these gaps because point-of-care testing does not explicitly occur in a single place within a state scope of practice act. The committee indicated that the

proposed statement calling for laws and regulations supporting pharmacists' point-of-care testing services would provide encouragement to NABP and state boards of pharmacy to make appropriate changes.

9. The committee reviewed current APhA policy related to laboratory testing. As a result, the committee determined that additional policy was necessary to specifically address the role of point-of-care testing services outside of existing APhA policy.
10. The committee agreed that use of the term *policies* includes company policies, payer policies, and so on that affect pharmacy practice, pharmacists' ability to provide point-of-care testing, and procedures for providing such testing.
11. The committee reviewed policies adopted by APhA–ASP on point-of-care testing. In developing the APhA–ASP policy, the APhA–ASP committee initially focused on only CLIA-waived tests. The APhA–ASP committee subsequently broadened the statement because of concern related to the unintended exclusion of tests that were used in pharmacies but were not CLIA-waived tests. The committee noted that the proposed policy included in this document recognizes not only the broad scope of point-of-care testing, but also the specific issues with CLIA-waived testing. Therefore, the committee agreed that issues related to CLIA-waived tests should be included in policy for APhA because their use in pharmacies varies at the state level.
12. The committee agreed the term *barriers* includes anything that would inhibit pharmacists' ability to perform point-of-care tests and also inhibit patient access to point-of-care tests. The committee discussed the need for required education on point-of-care tests and indicated that mandated education requirements would be a barrier. The committee also viewed inconsistencies in state laws and regulations related to CLIA-waived tests as a barrier.
13. The committee reviewed the current and new (2016) Accreditation Council on Pharmacy Education (ACPE) guidance documents for pharmacy education. The committee discussed the recent inclusion of the following language in the Standards related to point-of-care tests:

“schools and colleges of pharmacy should ensure graduates are competent to collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests.” The committee determined that such language would propel students toward having increased knowledge and skills in this area and that current policy on pharmacist education and training is adequate and no additional policy is needed.

14. The committee agreed that many education documents or tools have been created to assist in the implementation of point-of-care tests. The committee discussed resources from the Centers for Disease Control and Prevention, APhA, APhA Foundation, National Association of Chain Drug Stores, colleges of pharmacy, and state pharmacy associations. The committee did not want to encourage the creation of new resources, but rather the use of existing resources.
15. The committee identified a need to articulate the role of patients in the process of point-of-care testing. The committee determined that some states do not allow patients to legally request a point-of-care test without a prescription from a provider, thereby creating a potential barrier for patients wishing to take an active role in the management of their health. The committee discussed “*direct access testing*” in which a patient can request a test and a pharmacist’s professional judgment in that process. The committee determined that patients should be allowed to request the tests and that health professionals receiving the request should be allowed to use their professional judgment in determining the appropriateness of the test for the patients.
16. The committee agreed that the term *coverage* refers to insurance plan coverage for patients and that the term *payment for* refers to the direct reimbursement for services to the pharmacist who provided the point-of-care test and related clinical services.
17. The committee discussed how existing payment structures for other health care providers should be used to establish coverage of and payment for pharmacists providing point-of-care tests and related services.

18. The committee acknowledged that, depending on the state, pharmacists have the authority to write new prescriptions or modify existing drug therapy based upon test results. The committee discussed the lack of insurance coverage for a prescription written by a pharmacist after a point-of-care test has been rendered. The committee determined that this topic should be reviewed as a future policy topic because it goes beyond point-of-care testing.
19. The committee reviewed the role of credentialing in the process of offering point-of-care tests. The committee acknowledged that credentialing may be perceived as a barrier to offering such services, but then discussed use of proper policies and procedures when conducting these services, which could be achieved through education, resources, and appropriate regulations and procedures.

References

1. Gubbins PO, Klepser ME, Dering-Anderson AM, et al. Point-of-care testing for infectious diseases: opportunities, barriers, and considerations in community pharmacy. *J Am Pharm Assoc.* 2014;54(2):163–71.
2. Burley E, Klepser S, Klepser M. Opportunities for pharmacists to improve access to primary care through use of CLIA-waived tests. *Michigan Pharmacist.* 2014;52(2):8–11.
3. Rodis JL, Thomas RA. Stepwise approach to developing point-of-care testing services in the community/ambulatory pharmacy setting. *J Am Pharm Assoc.* 2006;46(5):594–604.

Point-of-Care Testing
Background Paper Prepared for the 2015–2016 APhA Policy Committee
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Issue

The APhA Board of Trustees has directed the 2015–2016 Policy Committee to recommend policy to the APhA House of Delegates related to pharmacists' involvement in point-of-care testing (POCT), including rapid diagnostic testing.

Summary of Key Concepts

- The pharmacy profession is working diligently to develop a sound, structured plan that will provide medication therapy management, chronic condition management, and other health and wellness services within contemporary health care. As health care continues to shift toward primary and preventive care, performing POCT may become a standard area of practice for all pharmacists.
- Pharmacists are permitted under federal law to perform POCT by using tests that have been waived by the Clinical Laboratory Improvement Amendments (CLIA).
- However, pharmacists' state-level scope of practice affects whether and how they can perform these tests at the state level; therefore, testing is inconsistently applied.
- Further education and training are needed to support pharmacist and student pharmacist participation in POCT programs.
- Pharmacist and student pharmacist participation in POCT programs could be an important component in expanding team-based models of care, improving patient access to needed services, and supporting the role of the pharmacist as a provider of patient care.
- The role of POCT in supporting the pharmacists' role on the health care team needs to be identified. Moreover, protocols, policies, procedures, and tools supporting consistency and continuity of care provision should be developed.
- The following potential barriers could affect pharmacist and student pharmacist participation in POCT programs: (a) lack of payment and coding mechanisms, (b) lack of standardized training and education across the profession, (c) lack of standardized documentation systems and follow-up procedures, (d) inconsistency in providing POCT services, (e) and perceived pushback from medical and other related health professionals.

Introduction

The pharmacy profession is at a crossroads. Efforts to expand the patient care activities of pharmacists to include areas of primary, preventive, and chronic care, while at the same time improving access, quality, and cost effectiveness of such care, have aligned with the profession's pursuit of recognition as health care providers under federal and state law. One such area of expanding patient care activities is the involvement of pharmacists and student pharmacists in POCT programs.

According to the Centers for Disease Control and Prevention (CDC), an estimated 7 million people have undiagnosed diabetes, 240,000 people have undiagnosed human immunodeficiency virus (HIV), and 800,000 people have undiagnosed hepatitis C.¹ All of those diseases are detectable by POCT, including rapid diagnostic testing (RDT) programs, and the early detection of these conditions can lead to better patient outcomes.

POCT programs can also contribute to the successful monitoring and management of various chronic diseases, thus helping address the increasing burden of chronic disease. With more than 60,000 community pharmacies in the United States, and an estimated 4,000 weekly patient visits per pharmacy, pharmacists undoubtedly have the access necessary to make a positive effect on the health and well-being of patients in various areas of patient care.²

Although some aspects of POCT programs have been standard practice in health care for a number of years, the participation of pharmacists in such programs has risen somewhat slowly in the past 10–15 years as pharmacists have become increasingly involved in direct patient care activities, disease-monitoring programs, and patient self-monitoring initiatives.²

A number of factors may have contributed to this relative lack of POCT program expansion, including, but not limited to, the following:²

- Pharmacists' lack of familiarity with POCT program processes
- Pharmacists' lack of physical assessment and specimen collection skills
- Low level of acceptance of pharmacists' by other health care providers
- Administrative burden of meeting state regulations, federal requirements, and other third-party demands
- Feasibility of incorporating POCT programs into the pharmacy workflow
- Financial considerations regarding testing equipment, supplies, and documentation programs
- Relatively limited financial incentives to provide such testing

In the past 10–15 years, a number of research projects have been implemented to demonstrate the positive effect that pharmacist-provided care services can have in the management of various disease states. One such venture, *Project ImPACT: Hyperlipidemia*, was a community pharmacy–based demonstration project that incorporated pharmacists to provide POCT. In that project, which was supported by the APhA Foundation, pharmacists in 26 community pharmacies and clinics used Cholestech LDX Analyzer devices to measure the achievement of National Cholesterol Education Program (NCEP) target lipid goals in 397 patients over approximately 2 years. At the end of that groundbreaking program, 90.1% of participants were observed to be compliant with medication therapy, and 62.5% of participants reached and maintained their NCEP target lipid goal at the end of the observation period.³

The burden of chronic disease is growing along with the aging of the population and the increasing complexity of the health care system. Pharmacists are in the perfect position to contribute to the care of patients through participation and leadership of POCT programs.

Because the terms *point-of-care testing* and *rapid diagnostic testing* are sometimes used interchangeably, the following general definition will be used within this discussion paper: POCT “involves performing a robust diagnostic test outside of a laboratory at or near the patient that provides a reliable result rapidly to aid in disease screening, diagnosis, and/or patient monitoring.”⁴ Examples of POCT include, but are not limited to, obtaining a serum creatinine level to gauge renal function; ordering a hemoglobin A1C level to determine blood glucose control; and performing RDT for the confirmation of a specific disease (e.g., testing for Group A *Streptococcus*, influenza, respiratory syncytial virus, hepatitis C, HIV).²

Legislative and Regulatory Considerations

Federal law does not specifically preclude pharmacist or student pharmacist participation in POCT. However, a number of state legislative and regulatory considerations should be considered with respect to participating in these services.

CLIA-Waived Tests

To ensure the accuracy, quality, and reliability of laboratory test results, the Clinical Laboratory Improvement Amendments were passed in 1988 and finalized in 1992. CLIA requires laboratories to meet standardized certification parameters in order to perform tests on human specimens. However, if a laboratory test could be performed with a “minimal level of complexity and low risk of erroneous results,” an exception could be granted to perform this testing in a nonlaboratory setting (e.g., pharmacy, clinic, or other nonlaboratory setting).^{2,5} Those excepted tests are known as *CLIA-waived tests*.^{2,5} Therefore, before initiating POCT services, pharmacies must obtain a CLIA Certificate of Waiver through their state office of the Centers for Medicare and Medicaid Services (CMS).⁴ Of note, in 2012–2013, only 14% of the approximately 60,000 community pharmacies in the United States were providing CLIA-waived POCT services.⁴

Of the 120 CLIA-waived laboratory tests available in the United States, a smaller number are generally considered appropriate for inclusion in most pharmacy-based POCT programs. Some of the POCT services that may be conducted in pharmacies include the following:^{2,4,6}

Cholesterol

- Group A *Streptococcus* (RDT)
- *Helicobacter pylori* (RDT)
- Hemoglobin A1C
- Influenza (RDT)
- International normalized ratio (INR)
- Serum chemistries (e.g., sodium, potassium, chloride)

For a full list of the CLIA-waived tests available in the United States, visit:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm.⁶

State Regulations

A major barrier to the widespread expansion and growth of pharmacist-led POCT programs is the variability and limitations of state legislation and regulation with regard to these initiatives. According to Gubbins et al., “if the practice act of a state does not explicitly address POC testing directly, such tests may be addressed under collaborative drug therapy management (CDTM) provisions in state regulations or statutes.”⁴ As of 2012, 44 states had a provision in their state pharmacy practice acts to allow for CDTM. Of those 44 states, only 19 (Arkansas, California, Colorado, Georgia, Idaho, Iowa, Louisiana, Maryland, Michigan, Montana, New Jersey, Nebraska, New Mexico, North Dakota, Oregon, Texas, Vermont, Washington, and Wyoming) had specific language in their CDTM provisions allowing for pharmacist participation in POCT programs. Of those 19 states, only 7 (California, Colorado, Georgia, New Jersey, North Dakota, Pennsylvania, and Washington) also had POCT-related provisions in their state pharmacy practice acts (outside of CDTM language).⁴

In a separate review by Gubbins et al., he found that eight states explicitly included POCT-related language in their respective pharmacy practice acts. In five of these states, the respective practice acts outlined specific POCT programs in which pharmacists are allowed to participate.⁴

Because conducting testing without a plan for follow-up or treatment is generally counterproductive, practitioners interested in offering POCT programs should become familiar with their state laws and regulations related to the provision of POCT. If applicable, they should also learn about participation in CDTM, collaborative practice agreements, initiation of standing orders, or implementation of treatment protocols. Although these areas are not inherently necessary in the provision of POCT programs, their inclusion can likely facilitate the effectiveness and efficiency of POCT programs.

Other Regulations

Because POCT programs can potentially increase pharmacist and student pharmacist exposure to bloodborne pathogens and other hazards, practitioners should also review regulations from the Occupational Safety and Health Administration (OSHA). OSHA regulations include language related to the use of appropriate personal protective equipment and the provision of adequate training, documentation, and emergency plans.⁵

Education and Training

According to Burley et al., more than 85% of pharmacists and student pharmacists who participated in a recent survey responded that they did not about CLIA-waived tests in school and “would not be comfortable discussing tests or test results with their patients or prescribers.” Further, a survey conducted by the Society of Infectious Diseases Pharmacists indicated that more than 66% of colleges of pharmacy did not include RDT-related information in their curricula.²

As with any evolving or expanding area of patient care, concerns arise about the availability of standardized, appropriate training in the development and implementation of pharmacist-provided POCT programs. Many schools and colleges of pharmacy have included aspects related to POCT in their curricula over the years. However, in its *Guidance for Standards 2016*, the Accreditation Council for Pharmacy Education (ACPE) included information encouraging schools and colleges of pharmacy to ensure graduates are competent to “collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests.”⁷ As a result of that recommendation to PharmD programs across the country, the expansion of POCT activities is expected to continue.

To assist in educating and training those practitioners already in the work force, individual national and state pharmacy associations have provided continuing education programs related to laboratory and POCT services. A number of state Boards of Pharmacy require related continuing education before participation in POCT and laboratory testing programs. For example, the Florida Board of Pharmacy requires pharmacists (consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree) who wish to order and evaluate laboratory tests in long-term care or home health settings to complete at least a 3-hour initial certification course and at least a 1-hour recertification course.⁸

In addition, the National Association of Chain Drug Stores (NACDS) recently partnered with clinicians from Ferris State University College of Pharmacy, University of Nebraska Medical Center College of Pharmacy, and Michigan Pharmacists Association to offer a 20-hour certificate training course related to POCT. The Community Pharmacy–Based Point-of-Care Testing Certificate Course provides community pharmacists, academicians, and other interested practitioners with the skills necessary to develop and implement a collaborative testing program for influenza, Group A *Streptococcus*, HIV, and hepatitis C. A Train-the-Trainer Program has also been developed to assist in expansion of the POCT and RDT initiatives across the country. For more information about this certificate program, visit <http://www.michiganpharmacists.org/resources/pointofcare>.⁹

Documentation and Follow-up

Although pharmacist-provided POCT can afford additional opportunities to affect patient health and well-being, interested practitioners should carefully consider how testing results should be documented and shared with other health care providers. Use of standardized forms and documentation procedures, such as subjective (data), objective (data), assessment, plan (SOAP) notes or other recordkeeping processes, can contribute to a patient’s continuity of care, provide legal evidence of the test(s) conducted and results obtained, and potentially provide proof of testing for billing purposes.⁵ Providers should use the

communications and documentation systems available to them. Although the electronic documentation of POCT data and exchange of information among providers is the preferred means of communication for these activities, the infrastructure to support the direct exchange of health information is still evolving. This direct interface will improve continuity of care and allow the physician and other health care providers to monitor the patient more effectively and efficiently.

At the same time that documentation and follow-up systems are being evaluated, special consideration should also be given to the potential connectivity of POCT devices used during patient testing. Many biotechnology companies have developed multiple-use POCT devices capable of administering multiple tests with one sample. Such devices may also be able to download patient testing results to individual electronic health records and testing site databases.

Payment and Coverage

As with other CLIA-waived tests, pharmacists providing POCT services can charge patients directly or potentially bill third-party payers (as long as the third-party payer is willing to pay for the test and state practice laws, regulations, and other documentation requirements are met). Although this ability to bill third-party payers is available—on a limited basis—the expansion of POCT programs has remained relatively low, especially in view of the length of time CLIA-waived tests have existed and the comparative ease of use in providing such tests.

From 2011 to 2013, Darin et al. evaluated the acceptability and feasibility of providing RDT for patients with HIV in two independent community pharmacies. Of the 69 participants screened, 37 were covered by third-party insurance, 13 were covered by Medicaid, 3 were covered by Medicare, and 14 had no insurance coverage. Within this group, 19 participants indicated they would be willing to pay for the HIV test, and 44 participants responded they might pay for the HIV test, depending on the cost. Approximately 80% of participants indicated they would be willing to pay \$16–\$20 or less for the HIV test, and 9% of participants stated they would pay \$30 or more.¹⁰ From the results of this study, one can infer that payment and coverage considerations are a major factor in patient acceptance of such testing, regardless of the perceived potential severity of the disease for which the patient is being tested. Further, as education and training programs are expanded across the country, professional stakeholders should continue outreach to policy makers, third-party plans, and other interested groups to ensure that pharmacist-provided POCT programs are included in future payment and coverage discussions.

Quality Improvement Initiatives

Recent changes to health care laws have included a greater focus on health care spending that improves patient outcomes and a greater scrutiny in spending that does not. A major effort to improve patient outcomes, while addressing fiscal responsibility, is the development of various quality improvement initiatives in all areas of the health care system. Although efforts to address health care quality have been made in various accreditation and process improvement programs over the years, specific programs and measures are now in place to address the improvement of patient outcomes by targeting pharmacy-related areas in health plans, Medicare, and Medicaid. Pharmacists can use POCT to help them track and aid patient progress toward meeting established therapeutic goals.

Pharmacy Quality Alliance Performance Measures¹¹

The Pharmacy Quality Alliance (PQA) has developed performance measures that are specific quality-related metrics applicable to POCT tools to assist pharmacists in monitoring and influencing patient care progress:

- Proportion of Days Covered (PDC)
- Adherence to Non-Warfarin Oral Anticoagulants

- Diabetes Medication Dosing (DOS)
- Primary Medication Non-adherence (PMN)
- Statin Use in Persons with Diabetes
- Medication Therapy for Persons with Asthma
- Use of High-Risk Medications in the Elderly (HRM)
- Use of Benzodiazepine Sedative Hypnotic Medications in the Elderly
- Drug-Drug Interactions
- Antipsychotic Use in Persons with Dementia—MDS
- Antipsychotic Use in Children Under 5 Years Old
- Cholesterol Management in Coronary Artery Disease
- Completion Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer
- Completion Rate for Comprehensive Medication Review
- Provision of Medication Therapy Management Services Post Hospital Discharge
- Readmission of Patients Provided Medication Therapy Management Services Post Hospital Discharge

Medicare Star Rating System^{12, 13}

Pharmacists' use of POCT in providing patient care services can assist them in helping patients achieve health outcomes, and ultimately contribute to quality measures. CMS uses a five-star quality rating system to measure Medicare beneficiaries' experience with their health plans and the overall health care system. This rating system applies to all Medicare Advantage (MA) plans: health maintenance organizations (HMOs), preferred provider organizations (PPOs), private fee-for-service (PFFS) plans, and prescription drug plans (PDPs). Because star ratings can affect plan revenue, reimbursements, and enrollment, the inclusion of pharmacy- and medication-related measures presents an opportunity for pharmacists to contribute directly to the rating of plans and the overall care received by patients.

Medicare Part D Star Ratings are based on measures of a health plan's rating across the following five domains:

1. Helping plan members stay healthy
2. Managing chronic conditions
3. Members' experience with their health plan (i.e., plan responsiveness, care, and quality)
4. Members' complaints or problems getting services, and improvement in performance
5. Health plan's customer service

In addition, Medicare Part C drug plans are rated on the following domains:

1. Drug plan customer service
2. Members' complaints or problems getting services, and improvement in performance
3. Members' experience with the drug plan (i.e., plan responsiveness, care, and quality)
4. Patient safety and accuracy of drug pricing

Although the star rating system domains do not specifically mention the role of pharmacists, the effect of pharmacists in "managing chronic conditions" through medication management activities is undeniable. Further, by becoming more involved in POCT programs, pharmacists can assist health plans in meeting their star measures by playing a larger role in "helping plan members stay healthy," through providing vaccines, contributing to infectious disease testing surveillance, and offering various screening services. Programs that have health plans in collaboration with pharmacies and pharmacists to improve star ratings metrics, primarily adherence metrics, are emerging in the marketplace. Thus, the feasibility of similar programs focused on POCT exists.

Conclusion

In view of the recent passage of the Patient Protection and Affordable Care Act, the pharmacy profession's push for provider status, and the need for improved patient access to quality health care services (i.e., POCT programs), pharmacists are positioned to become more fully integrated within the U.S. health care system. However, with this opportunity comes the potential for further legislative and regulatory oversight, additional professional education requirements, increased administrative and financial burdens, workflow concerns, and even public scrutiny as pharmacists take on these expanded patient care roles. By being proactive in setting professional policy about participation of pharmacists and student pharmacists in POCT programs, the pharmacy profession will be in a better position not only to serve patients, but also to support the overall expansion of pharmacist-provided care.

References

1. Olsen K et al. Use of rapid diagnostic tests and point-of-care diagnostics by pharmacists. Nebraska Pharmacists Association. Available at: www.npharm.org/Files/Newsandevents/AnnualConvention/2014Handouts/CPESession03.pdf. Accessed January 9, 2015.
2. Burley E, Klepser S, Klepser M. Opportunities for pharmacists to improve access to primary care through use of CLIA-waived tests. *Mich Pharm*. 2014;52(2):8–11.
3. Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia. *J Am Pharm Assoc*. 2000;40:157–65.
4. Gubbins PO, Klepser ME, Dering-Anderson AM, et al. Point-of-care testing for infectious diseases: opportunities, barriers, and considerations in community pharmacy. *J Am Pharm Assoc*. 2014;54(2):163–71.
5. Rodis JL, Thomas RA. Stepwise approach to developing point-of-care testing services in the community/ambulatory pharmacy setting. *J Am Pharm Assoc*. 2006;46(5):594–604.
6. U.S. Food and Drug Administration. CLIA currently waived analytes. Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm. Accessed August 26, 2015.
7. Accreditation Council for Pharmacy Education. Guidance for the accreditation standards and key elements for the professional program in pharmacy leading to the doctor of pharmacy degree. Available at: <https://www.acpe-accredit.org/pdf/GuidanceforStandards2016FINAL.pdf>. Accessed August 24, 2015.
8. Florida Board of Pharmacy. The Florida Statutes Chapter 465. Available at: <http://floridaspharmacy.gov/resources/>. Accessed October 2, 2015.
9. Michigan Pharmacists Association. Point-of-care testing. Available at: www.michiganpharmacists.org/resources/pointofcare. Accessed July 2, 2015.
10. Darin KM, Klepser ME, Klepser DE, et al. Pharmacist-provided rapid HIV testing in two community pharmacies. *J Am Pharm Assoc*. 2015;55(1):81–88.
11. Performance Quality Alliance. PQA performance measures. Available at: <http://pqaalliance.org/images/uploads/files/PQA%20measuresJuly2015.pdf>. Accessed August 24, 2015.
12. What are CMS star ratings? Available at: <https://www.healthplanofnevada.com/~media/Files/HPN/pdf/Provider-Services/STAR-Rating/What-Are-CMS-Star-Ratings.ashx> Accessed August 25, 2015.
13. Smart Retailing. Star ratings explained. Available at: smartretailingrx.com/regulatory-public-affairs/star-ratings-explained/. Accessed August 24, 2015

Relevant APhA Policies

2013, 2008, 1987 *Sale of Home-Use Diagnostic and Monitoring Products*

1. APhA supports the need to protect the health of people in the United States through proper instruction in the safe and effective use of the more complex home-use diagnostic and monitoring products.
 2. APhA supports the promotion of pharmacists as widely available and qualified health care professionals to advise patients in the operation of home-use diagnostic and monitoring products.
- (Am Pharm NS27(6):424 June 1987) (Reviewed 2003) (JAPhA NS48(4):470 July/August 2008) (JAPhA 53(4):366 July/August 2013)

2012, 2003 *The Pharmacist's Role in Laboratory Monitoring and Health Screening 2012, 2003*

1. APhA supports pharmacist involvement in appropriate laboratory testing and health screening, including pharmacists directly conducting the activity, supervising such activity, ordering and interpreting such tests, and communicating such test results.
 2. APhA supports revision of relevant laws and regulations to facilitate pharmacist involvement in appropriate laboratory testing and health screening as essential components of patient care.
 3. APhA encourages research to further demonstrate the value of pharmacist involvement in laboratory testing and health screening services.
 4. APhA supports public and private sector compensation for pharmacist involvement in laboratory testing and health screening services.
 5. APhA supports training and education of pharmacists and student pharmacists to direct, perform, and interpret appropriate laboratory testing and health screening services. Such education and training should include proficiency testing, quality control, and quality assurance.
 6. APhA encourages collaboration and research with other health care providers to ensure appropriate interpretation and use of laboratory monitoring and health screening results.
- (JAPhA NS43(5)Suppl. 1:S58 September/October 2003) (Reviewed 2007) (Reviewed 2009) (Reviewed 2010) (JAPhA NS52(4):460 July/August 2012) (Reviewed 2013)

2011 *The Role and Contributions of the Pharmacist in Public Health*

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

(JAPhA NS52(4):482 July/August 2011) (Reviewed 2012)

1987 *Pharmacist Training in Medical Technology 1981*

1. APhA supports the education and training of pharmacists in the ordering and interpretation of laboratory tests as they may relate to the usage, dosing, and administration of drugs.
 2. APhA opposes requiring certification of pharmacists as medical technologists for the practice of pharmacy.
- (Am Pharm NS21(5):40 May 1981) (Reviewed 2003) (Reviewed 2006) (Reviewed 2011)

1989 *Pharmacy-based Screening and Monitoring Services*

APhA supports projects that demonstrate and evaluate various pharmacy-based screening and monitoring services.

(Am Pharm NS29(7):463 July 1989) (Reviewed 2006) (Reviewed 2007)(Reviewed 2013)

Relevant APhA-ASP Policy

2015.3 APhA-ASP Point-of-Care Testing

1. APhA–ASP supports state and federal legislation that allows pharmacists and student pharmacists to provide point-of-care tests and related clinical services—through appropriate protocol and in collaboration with other members of the health care team— to increase patient access to care and screen or monitor for indications requiring care follow-up, referral, or therapy adjustment.
2. APhA-ASP supports the incorporation of point of care testing education and training throughout the pharmacy curriculum to train student pharmacists on appropriate administration of tests and management of results, including but not limited to, relevant counseling, documentation, reporting, and follow-up.
3. APhA-ASP encourages the development of continuing education and training programs to enhance existing practitioner understanding and use of point of care testing.
4. APhA-ASP encourages all stakeholders, including, but not limited to, employers, patients, pharmacists, community pharmacies, health-systems, and third party payers to develop a compensation model recognizing the value and cost of pharmacist-provided point-of-care testing and the provision of related clinical services and is both financially viable and in the best interest of patients.
5. APhA-ASP encourages all public health stakeholders and agencies to promote patient awareness of pharmacist-provided point of care testing and related clinical services for the purpose of improving community surveillance of disease prevalence and incidence.

Policy from Related Organizations

College of American Pathologists

Point of Care Testing Policy Synopsis

Point of care testing (POCT) is defined as laboratory testing that takes place at or near the site where the patient is located. In order for a POCT program to provide quality patient care, it must be developed by all stakeholders, with guidance and leadership from pathologists, and consider cost-benefit analysis and appropriate technology. The application of new non-traditional technologies also should conform to these principles. Even for simple methods performed outside of the central laboratory, the expertise of pathologists and other laboratory professionals is essential for quality patient care.

Policy

Point of Care Testing (POCT) is any type of laboratory testing that takes place at or near where the patient is located. The College of American Pathologists (CAP) recognizes that POCT is an integral part of laboratory medicine and certain basic principles must apply: Quality of patient care and patient safety are the highest priorities. Therefore, POCT must meet the accreditation standards of the College of American Pathologists, or other accrediting agencies recognized by the Department of Health and Human Services. POCT should be under the supervision of the laboratory director to ensure quality of the testing and appropriate training of testing personnel. Development of these programs should actively involve all participants for either in-hospital or offsite testing, and should include laboratory staff, nursing, medical staff, administration, and other health care professionals. Efforts should be made to quantify and compare all costs and benefits associated with POCT and other testing modalities. Gathering of such data will allow optimal decision making regarding testing strategies. New technologies for testing non-traditional specimens or non-invasive measurements are likely to have growing application in point-of-care settings. In the interest of quality patient care, the application of new testing technologies should conform to the points listed above. Interoperability should be developed or expanded for existing and new POCT technologies to provide better oversight and incorporation of results into the electronic medical record.

Revision History

Adopted November 1993
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Retitled May 1999
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Revised November 1999
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Reaffirmed September 2013

Potential References for the Policy Committee

Goble JA, Rocafort PT. Point-of-Care Testing: Future of Chronic Disease State Management? [*J Pharm Pract.*](#) 2015 Jun 19. pii:0897190015587696. [Epub ahead of print]

Gutierrez SL, Welty WE. Point-of-care testing: an introduction. [*Ann Pharmacother.*](#) 2004 Jan;38(1):119–25.

[Sherman EM](#), [Elrod S](#), [Allen D](#), [Eckardt P](#). Pharmacist testers in multidisciplinary health care team expand HIV point-of-care testing program. [*J Pharm Pract.*](#) 2014 Dec;27(6):578–81. doi:10.1177/0897190013514090.

2015–2016 APhA Policy Committee Report

Medication Optimization Services within the Patient Care Process

The committee recommends that the association adopt the following statements:

1. APhA asserts that pharmacist-directed “medication optimization services” encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access.
[Refer to Summary of Discussion Items 1, 2, 3.]
2. APhA calls for the interprofessional development and adoption of a framework to describe the spectrum of medication optimization services.
[Refer to Summary of Discussion Items 4, 5, 6, 7, 8.]
3. APhA calls for pharmacists and student pharmacists to provide medication optimization services in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process in any practice setting.
[Refer to Summary of Discussion Items 8, 9, 10.]
4. APhA supports technologies and standards for multidirectional data exchange related to medication optimization services that facilitate timely communication among pharmacists, patients, other health care providers, pharmacies, health systems, and payers.
[Refer to Summary of Discussion Item 11.]
5. APhA encourages health care providers, including pharmacists, to refer patients for pharmacist-provided medication optimization services, as appropriate.
[Refer to Summary of Discussion Item 12.]
6. APhA supports coverage of and payment for pharmacist-provided patient care services, including medication optimization services within traditional and value-based payment systems in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacist’s Patient Care Process.
[Refer to Summary of Discussion Items 8, 13.]

Summary of Discussion

1. The committee reviewed terminology used for more than the past 20 years and the relationship of each term to the current provision of patient care services. The committee determined that the term *medication optimization* encompassed all of these terms, including pharmaceutical care, medication therapy management, medication management, medication adherence services, and so on and is not a substitute term.
2. The committee discussed the current use of the term *medication optimization*. The committee noted that this term has an international presence together with growing use by government agencies within the United States.
3. The committee agreed that the term *access* encompasses cost and availability of a medication or service for a patient.
4. The committee did not want to define a new term within the House of Delegates. Instead, the committee focused on what services could be considered medication optimization services based on a framework of how those services are delivered to the patient.
5. The committee reviewed the terms *interprofessional* and *interdisciplinary* and agreed that although pharmacists are best equipped to provide medication optimization services, other health care practitioners need to understand and embrace the pharmacists' role in medication optimization.
6. The committee discussed the importance of having consensus regarding the terminology used to describe pharmacist services. The committee highlighted the confusion related to variations in implementing medication therapy management services. The committee reviewed the Pharmacy Practice Activity Classification as a resource that categorizes pharmacy services, but agreed that a more formal framework was necessary.

7. The committee considered using the term *define* in place of *describe* to determine the action related to a framework regarding the spectrum of medication optimization services. The committee agreed on the difficulty in defining every service included within medication optimization services in contrast with describing them along a spectrum of low patient contact to high patient contact.
8. The Joint Commission of Pharmacy Practitioners (JCPP) was established in 1977 and serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners and invited liaison members. JCPP members are the Academy of Managed Care Pharmacy, the Accreditation Council for Pharmacy Education, American Association of Colleges of Pharmacy, American College of Apothecaries, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Alliance of State Pharmacy Associations, National Association of Boards of Pharmacy, and National Community Pharmacists Association.
9. The committee carefully selected the verb *calls* to elicit a call to action rather than using a less forceful verb such as *encourages* or *supports*. In view of the current issues with terminology and the desire by pharmacists for support of the JCPP Patient Care Process, the committee acknowledged its preference for the profession to avoid any delay in addressing the identified issues.
10. The committee reviewed the JCCP's Pharmacists' Patient Care Process and modeled the proposed policy wording "in any practice setting" after it. The committee noted that the process was designed to apply to any practice setting.
11. The committee discussed the importance of closing the information loop with other members of the health care team and reviewed current APhA policy related to interoperability of patient health information. Because current APhA policy is focused on transitions of care, the committee specifically noted the need for data exchange among all stakeholders related to medication optimization service delivery and payment, beyond care transitions only.

12. The committee discussed the need for an established patient referral system for use by health care providers. The committee acknowledged that the referral system should allow pharmacists to refer patients among other pharmacists or between pharmacists and other health care providers, acknowledging patient complexity, access issues, and skill sets of individual team members.
13. The committee discussed the history and differing models of value-based and pay-for-performance systems, noting that such systems vary from traditional models in that they use incentives to improve quality and reduce costs, thereby increasing value. The committee acknowledged that the Centers for Medicare and Medicaid Services plans for 75% of payments to be value based by 2020. The committee indicated that coverage of and payment for pharmacist-provided medication optimization services needs to be incorporated in whatever system is developed.

Medication Optimization Services within the Patient Care Process
Background Paper Prepared for the 2015–2016 APhA Policy Committee

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Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2015–2016 Policy Committee to recommend policy to the APhA House of Delegates related to pharmacists' involvement in medication management services, including services related to medication adherence activities, medication therapy management, and the Pharmacists' Patient Care Process.

Summary of Key Concepts

- Medication management services terminology is variable and is not applied in a standardized manner and not widely understood by health care providers, patients, and payers.
- Medication management services do not currently have widespread recognition as essential and integral patient care services.
- Medication management services are not uniformly recognized as an essential benefit for health care coverage and are not broadly supported by established practice-specific procedures and protocols across the pharmacy profession.
- Meaningful quality metrics are needed to measure the value of medication management services, especially in new value-based payment and delivery models.
- Pharmacists do not provide medication management services using a consistent process of care across the pharmacy profession, and documentation of services by pharmacists varies greatly.
- Established referral systems involving physicians and other health care providers, including pharmacists, do not currently exist.
- Medication synchronization and the medication-related services incorporated in the Appointment-Based Model are emerging, but they are somewhat variable across the pharmacy profession.
- The Appointment-Based Model could benefit from profession-wide consensus on the identification of appropriate patients, the definition of the services that should be provided, and a well-defined business model to support broad adoption in practice.
- The role of medication therapy review and other medication management services and the business model to support them in the Appointment-Based Model services is not well-established.

Introduction

Pharmacists' medication-related patient care services are core to pharmacists' training and the value they supply as health care providers and members of the health care team. These services, broadly termed *medication management services*, include a spectrum of services to optimize medication and health outcomes for individual patients. Within this spectrum are services related to medication therapy management, comprehensive medication management, Medicare Part D Medication Therapy Management, medication adherence, medication reconciliation, medication synchronization, and care transition, as well as the medication-related services incorporated into the Appointment-Based Model. Challenges exist across the health care system with regard to disparate medication management terms and terminology and a resulting confusion about the definition and content of these services. Because of the lack of widely adopted definitions, physicians, other health care providers, patients, payers, and even pharmacists cannot clearly understand or consistently communicate the terminology. Additionally, this ambiguity in terminology has led to not only difficulty in measuring the effect and outcomes of the

services provided, but also a lack of attributed value to the health care system. Further, it has contributed to the lack of recognition of these services as a covered essential benefit among health plans and emerging delivery models. Taking steps to build awareness and better clarify accepted and pharmacy-supported definitions of pharmacists' services in order to optimize medication use is essential.

Medication management services provided by pharmacists may be augmented by a variety of other related services, including health and wellness services and chronic condition (disease) management. Regardless of the service delivered, establishing that a consistent process of care is the foundation for providing consistency in the marketplace and measuring the value of pharmacist-delivered care is essential. This is important especially with the emergence of value-based payment models in the health care system. The Joint Commission of Pharmacy Practitioners recently adopted the Pharmacists' Patient Care Process, which is designed to be the contemporary practice framework for pharmacists' patient care delivery, including medication management.¹

As pharmacists develop medication management services, consideration must also be given to the implementation of standardized practice models similar to those of other health care providers. This approach includes (a) implementing standardized processes for medication management that lead to consistent care across patient care settings, (b) delivering care within an individual practice through practice-specific procedures and protocols developed and documented within the practice, (c) documenting the care provided in a patient-specific health record accessible to all providers within the practice providing care to patients, and (d) establishing a referral system in which patients identified by their physicians or other health care providers can efficiently receive their needed medication management services from a pharmacist in a coordinated and efficient manner. The profession has yet to fully achieve these goals. However, as a profession, pharmacists must strive to provide consistent medication management service delivery that reliably meets the expectations of patients and caregivers, other health care providers, and payers.

When evaluating patients' medication regimens, a pharmacist assesses each medication for appropriateness, efficacy, safety, and adherence.¹ A comprehensive assessment must include all of these elements. If problems are identified, then the patient may receive specific services to address the problem(s). For adherence problems, a variety of programs are emerging in the marketplace, including medication synchronization, adherence programs targeted to specific medications, automated refill programs, special packaging, and the Appointment-Based Model (ABM) for care delivery. Adherence services may include a variety of elements, based on the needs of the individual patient. Each adherence program must have a design that clearly defines the elements to ensure consistent care delivery from pharmacist to pharmacist and from one patient care practice to another. Currently, these programs and models vary. With the emerging ABM, clarification and consensus are needed on which elements of the ABM service will be in the marketplace; whether medication management services, including medication review, are included and financially sustainable; and how the most appropriate patients are identified and enrolled.

Medication management has many issues. This paper focuses on those related to the areas of definitions and terminology and implementation in practice.

Definitions and Terminology

Medication-Related Services

Medication-related services encompass medication management, which involves a spectrum of services to optimize medication and health outcomes for individual patients. This spectrum includes services such as medication therapy management, comprehensive medication management, Medicare Part D Medication

Therapy Management, medication adherence, medication reconciliation, medication synchronization, and care transition, as well as the medication-related services incorporated into ABM.

Medication Therapy Management

Although pharmacists' medication-related clinical services had been delivered in various settings for several decades, the passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003 introduced medication therapy management (MTM) as a covered benefit and included specific mention of pharmacists as providers of MTM in the Social Security Act.² Under the MMA, each Medicare Part D prescription drug plan (PDP) sponsor was mandated to develop an MTM program to offer to targeted Medicare beneficiaries. Targeted beneficiaries, as defined in the law, are those covered beneficiaries who

- Have multiple chronic conditions
- Take multiple Part D medications
- Are projected to meet an anticipated annual spending threshold on their Part D medications

The law stated that MTM may be provided by pharmacists (the only provider specifically referenced). It also provided some guidance on the MTM program elements that could be provided to targeted beneficiaries as follows:

- Promote enhanced enrollee understanding through beneficiary education, counseling, and other means that promote the appropriate use of medications and reduce the risk of potentially adverse events from the use of medications.
- Increase enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, compliance programs, and other appropriate means).
- Detect adverse drug events, including patterns of overuse and underuse of prescription drugs.

Beyond these elements, a consensus definition of MTM in the marketplace was absent at the time the act was passed. Policy makers sought guidance on the meaning of MTM and the way it should be delivered.³ In 2004, a consortium of 11 national pharmacy organizations agreed on a definition of MTM that included an array of activities that could be performed as part of MTM services based on individual patient need⁴: "Medication therapy management (MTM) is a distinct service or group of services that optimizes therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication product."

An important aspect of the profession's consensus MTM definition is its much broader application and service level than the current Medicare Part D MTM benefit.

To provide further guidance, in 2005, APhA and the NACDS (National Association of Chain Drug Stores) Foundation developed a foundational service model describing five core elements of an MTM service, *Medication Therapy Management in Community Pharmacy Practice: Core Elements of an MTM Service* (version 1.0),⁵ that would serve as a guide for the creation of new MTM programs. The MTM Core Elements Model was updated in 2008 and published as *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model* (version 2.0) in the *Journal of the American Pharmacists Association* (JAPhA).⁶ The five elements of the model are as follows:

- Medication therapy review
- Personal medication record
- Medication-related action plan (for the patient)
- Intervention or referral
- Documentation and follow-up

The core elements serve as the basic foundation on which to build MTM services and program offerings and are designed to provide consistency in the standard service delivery model implemented for patients. Standard care elements that are part of this model include performing medication reviews (comprehensive or targeted), documenting care, and following up or referring a patient for additional care. The model also includes two elements that provide tangible deliverables for patients: an up-to-date medication list and a patient-centered medication action plan to assist a patient in effectively managing his or her medications. Additional patient care functions such as disease management and prevention, wellness activities, and those activities facilitated by collaborative practice agreements (such as initiating and modifying therapy and ordering laboratory tests) could build on the core elements model according to an individual state's scope of practice. The MTM Core Elements Model is aligned with the MTM Consensus Definition, which advocates for services that should be based on the individual needs of a patient and coordinated with the other health care services the patient is receiving.

When the Medicare Part D MTM benefit went into effect in 2006, the Centers for Medicare and Medicaid Services (CMS) allowed prescription drug plans significant flexibility in the design of their MTM programs. Because MTM was not defined well, CMS reasoned that program sponsors could experiment in the way patients were targeted, programs were designed, and MTM was delivered. As a result, the targeting criteria, method of delivery (telephonic versus face-to-face conversation), and types of MTM services (from medication therapy management using the core elements to mailed educational brochures) varied widely.^{7,8} As the Part D benefit matured, as innovation by programs occurred, and as CMS collected data on MTM service delivery and effect, refinements were made and more standardization was gradually introduced into the MTM program, especially that related to beneficiary targeting criteria. Since 2009, CMS has released MTM fact sheets that provide a variety of statistics about MTM enrollment, delivery, and outcomes.³

In 2009, the Patient Protection and Affordable Care Act (PPACA) contained provisions that improved the Medicare Part D MTM program such as a required annual person-to-person comprehensive medication review, targeted quarterly monitoring (no required patient interaction), and a standardized medication action plan and personal medication list for a patient.⁹ Eligible beneficiaries continue to be targeted for MTM by the Part D plans based on plan-specific criteria (that meets CMS requirements), and beneficiaries have the choice to opt out of receiving MTM services, including the annual comprehensive medication review. PPACA also included a provision for testing MTM through a grant program (not funded to date) and various mentions of pharmacists and MTM services in several new programs (outside of Part D MTM).¹⁰

On September 28, 2015, the CMS Center for Medicare and Medicaid Innovation (CMMI) announced the Medicare Part D Enhanced Medication Therapy Management model. According to CMMI:

This Enhanced MTM model offers an opportunity and financial incentives for basic stand-alone Part D Prescription Drug Plans (PDPs) in selected regions to offer innovative MTM programs in lieu of the standard CMS MTM model, aimed at improving the quality of care while also reducing costs. As part of the “better care, smarter spending, healthier people” approach to improving health delivery, CMS will test changes to the Part D program that aim to achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in MTM targeting and interventions.

Innovative models will be tested in five regions. Many of these strategies are those advocated by members within the pharmacy profession, including APhA, and include plans such as physician referral for MTM, better coordination of MTM with the patient's health care, and use of pharmacists in physician office practices and community pharmacies.¹¹

While the Medicare Part D MTM benefit has been evolving, MTM programs outside the Medicare program have also emerged in several state Medicaid programs, some private sector and self-insured employer programs, and physician office practices and clinics. For example, the longstanding Minnesota Medicaid MTM program pays pharmacists to provide care to targeted Medicaid patients with one or more chronic conditions taking three or more prescription medications. The Minnesota MTM benefit is more aligned with the pharmacy profession's MTM consensus definition, has broader targeting criteria, and promotes a comprehensive approach to care that includes follow-up visits as necessary.¹² The variability in program design and terminology has caused confusion inside and outside the pharmacy profession. The authors of one study attempting to describe the MTM services in Minnesota remarked that “the lack of a comprehensive description of the current level of services could hinder growth, especially as new graduates begin their professional careers. A current description of MTM practices and practitioner characteristics is needed to maintain progress.”¹³

Comprehensive Medication Management

The Patient-Centered Primary Care Collaborative (PCPCC) developed a framework for integrating comprehensive medication management into the patient-centered medical home. Comprehensive medication management is defined as the standard of care that ensures each patient's medications (prescription, nonprescription, alternative, and traditional medications; vitamins; or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended. PCPCC developed a resource guide, *The Patient-Centered Medical Home: Integrating Medication Management to Optimize Patient Outcomes*, that outlines the comprehensive medication management process.¹⁴

MTM Research Evidence

Variability in MTM service delivery and MTM terminology has also affected the ability to measure the effect of pharmacists' delivered MTM services. The term *medication therapy management* is often equated with the service requirements of Medicare Part D MTM, whereas private sector or state Medicaid programs using the same term may offer more robust MTM services to their beneficiaries (e.g., Minnesota Medicaid MTM program). Likewise, research studies on MTM often use a variety of different terms to characterize MTM interventions and do not use a standardized format to describe key components of MTM service delivery such as method of delivery, type of initial visit, type and quantity of follow-up visits, type and intensity of services delivered, and so on.

In 2014, a systematic review of MTM studies, Medication Therapy Management Interventions in Outpatient Settings, conducted by the Agency for Healthcare Research and Quality, found limited evidence for the effectiveness of MTM programs, primarily because of heterogeneity resulting from wide variations in populations and interventions. The review authors went on to explain that there are two important needs for efforts to systematically review MTM programs. The first is for researchers to specify the MTM intervention based on existing definitions, taxonomies, or service models. The second is to develop consensus guidelines for describing intervention features and fidelity of intervention delivery in publications reporting findings from evaluation studies. Progress on these two steps would enable systematic reviews to differentiate better between different types of services and avoid the problem of overgeneralizing review results.¹⁵

In 2014, Avalere Health released a report, Exploring Pharmacists' Role in a Changing Healthcare Environment, that was also a systematic review of the literature to examine the evidence for “the types of services that pharmacists can provide, and how a shifting landscape may affect the demand for these

services in the future.”¹⁶ Evidence was presented that pharmacists’ medication management services have been shown to improve adherence and clinical outcomes for patients with certain chronic diseases. Aspects of pharmacist-provided medication reconciliation, preventive care services, and educational and behavioral counseling services were also shown to provide benefits for emerging team-based care models. One of the findings in the key takeaways for medication management involved reporting: “New research evaluating pharmacist-provided medication management should diligently identify and standardize reporting of all relevant component services being delivered within these programs, as this can help inform policy and quality improvement efforts.”¹⁶

The previously mentioned systematic reviews also focused on the lack of randomized, controlled studies that have sufficient numbers of patients to stand up to the scrutiny of agencies such as CMS and Agency for Healthcare Research and Quality. Traditionally, pharmacy researchers have not been beneficiaries of large grants that would permit these types of studies. A 2014 review of MTM studies noted that “evidence suggests that MTM services are a promising way to manage complex patients, but there are gaps in the literature largely because of the limited number of studies with strong designs. Stronger evaluation of MTM programs is warranted.” The authors continued to explain that “most studies lacked rigorous design and had limited control groups” and that “taken together, comprehensive benefits of MTM economic outcomes remain inconclusive.” Although noting that the “broad goals” and “variety of designs” among MTM programs make assessment of these programs challenging, the authors indicated that overcoming the key barrier of reimbursement required better-designed and more comprehensive studies on MTM benefits.¹⁷

Summary

As a result of the disparate MTM terms and terminology, confusion exists about the definition and content of these services. Thus, key stakeholders such as physicians, other health care providers, patients, payers, and even pharmacists lack a clear understanding of these services and often do not recognize MTM as an essential and integral patient care service. Additionally, this ambiguity in terminology has resulted in both difficulty in measuring the effect and outcomes of MTM services and a lack of attributed value within the health care system. It also has contributed to the absence of recognition of MTM services as an essential health benefit for health care coverage.

Implementation in Practice

Medication management services provided by pharmacists may be provided alone or may be augmented by a variety of other related services, including health and wellness services and chronic condition (disease) management. Pharmacists must use a consistent process of care in delivering these services, regardless of the service delivered. A consistent process of care is the foundation for allowing the public to gain uniform expectations of pharmacists’ services and for measuring the value of care delivered. This is important especially with the emergence of value-based payment models in the health care system. The recently adopted Joint Commission of Pharmacy Practitioners’ (JCPP) Pharmacists’ Patient Care Process is designed to be the contemporary practice framework for pharmacist care delivery, including medication management.

Pharmacists’ Patient Care Process

The JCPP approved the Pharmacists’ Patient Care Process in May 2014 with the intention of standardizing how the pharmaceutical care model is taught and practiced. Most health care providers operate under a standardized patient care process, but until the JCPP’s approval, pharmacists had not had a consistently applied and delivered process of their own.¹ With the future of health care necessitating team-based, outcome-focused, and cost-effective approaches, articulation of the pharmacist’s care process

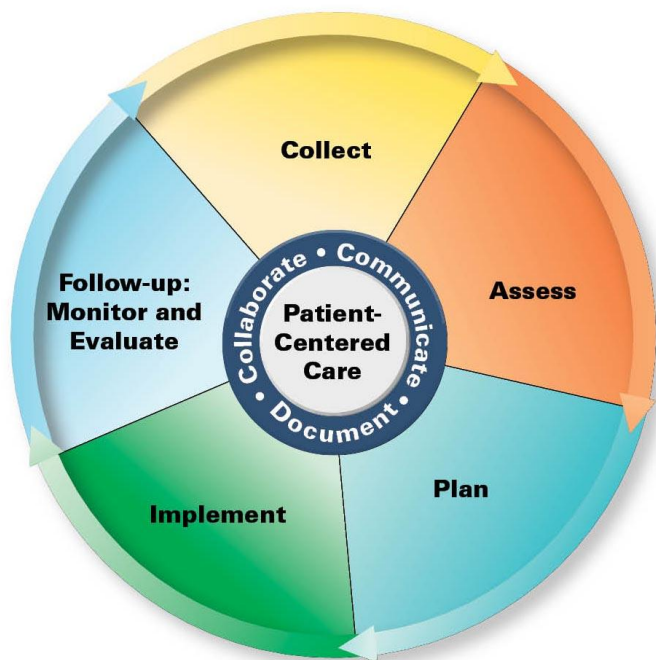
to other members of the health care teams and patients and facilitation of consistency for patients and the health care system were imperative. Developed by using the pharmaceutical care model and other key source documents, the Pharmacists' Patient Care Process was created to do the following:

- Promote consistency across the profession
- Provide a framework for delivering patient care in any practice setting
- Operate as a contemporary and comprehensive approach to patient-centered care delivered in collaboration with other members of the health care team
- Apply to a variety of patient care services delivered by pharmacists, including medication management

The key components of the Pharmacists' Patient Care Process are as follows: Collect, Assess, Plan, Implement, and Follow-up: Monitor and Evaluate (Figure 1). This cycle requires a pharmacist to “collaborate, communicate, and document” throughout the care process as a member of the health care team, all with the patient at the center of care. The foundational components of the process are as follows:

- Establishment of patient-pharmacist relationship
- Engagement and effective communication with a patient, family, and caregivers
- Continual collaboration, documentation, and communication with physicians and other health care providers
- Enhancement of process by interoperable information technology systems that facilitate effective and efficient communication

Figure 1. Key Components of the Pharmacists' Patient Care Process¹



Overview of Components

Collect: The pharmacist assures the collection of necessary subjective and objective information about the patient in order to understand the relevant medical and medication history and clinical status of the patient. Information may be gathered and verified from multiple sources. The information collected may include the following:

- A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements
- Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings
- Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that impact access to medications and other aspects of care

Assess: The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care. The assessment may include the following:

- Each medication for appropriateness, effectiveness, safety, and patient adherence
- Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care
- Immunization status and the need for preventive care and other health care services, where appropriate

Plan: The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence based and cost-effective.

The plan will include the following:

- Addresses medication-related problems and optimizes medication therapy
- Sets goals of therapy for achieving clinical outcomes in the context of the patient's overall health care goals and access to care
- Engages the patient through education, empowerment, and self-management
- Supports care continuity, including follow-up and transitions of care as appropriate

Implement: The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver. The pharmacist will engage in the following:

- Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration
- Initiates, modifies, discontinues, or administers medication therapy as authorized
- Provides education and self-management training to the patient or caregiver
- Contributes to coordination of care, including the referral or transition of the patient to another health care professional
- Schedules follow-up care as needed to achieve goals of therapy

Follow-Up: Monitor and Evaluate: The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed. The pharmacist may monitor and evaluate the following:

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

Adoption and implementation of the Pharmacists' Patient Care Process by the profession is in its early stages with national and state pharmacy organizations and with colleges of pharmacy through the revised accreditation standards of the Accreditation Council for Pharmacy Education (ACPE), which is committed to integrating the care process in education programming and care delivery. Members of each pharmacy practice area will assess how they will integrate this care delivery approach into their practices. JCPP member organizations have undertaken activities to support pharmacists' efforts to implement the patient care process:

- The Pharmacists' Patient Care Process has been included in the ACPE 2016 standards, which go into effect in July 2016.¹⁸ This inclusion is a major asset to JCPP's goal of providing consistency in the teaching of the patient care process. The new standard requires curriculum reform for didactic, experiential, and extracurricular learning to include the Pharmacists' Patient Care Process. Assessment of how well the process has been implemented within curricula can begin in Fall 2016, which will facilitate understanding of the best methods of incorporation and a potential standard that could be used going forward.¹⁹ ACPE also educated accredited continuing education providers about the process and encouraged those providers to incorporate the process into educational programs for pharmacists.
- The process is included in the newly revised American Society of Health-System Pharmacists' PGY1 residency accreditation standards and will be included in future revisions of the other residency accreditation standards.
- Numerous presentations are being delivered across the country in various formats to educate pharmacists about the process. These include education of pharmacists who are participating in Alliance for Integrated Medication Management and Center for Medicare and Medicaid Innovation projects.
- The Pharmacy Health Information Technology (HIT) Collaborative is incorporating the process into structured electronic documents that can be shared with other providers using the electronic health information exchange.
- The Pharmacy Quality Alliance is including consideration of the process in the development of new medication-related quality metrics.
- The process is being incorporated into tools for pharmacists, such as a tool to identify gaps in diabetes care developed by a national patient safety organization.

The Pharmacists' Patient Care Process is designed for use in all pharmacy practice settings where patient care is delivered. APhA has published a book, *How to Implement the Pharmacists' Patient Care Process*, that provides detailed explanations of the steps in the process and, perhaps most important, case-studies and exercises that show how the process can be integrated into different pharmacy settings for different types of services.²⁰ A community pharmacy example shows how the process can be applied during a comprehensive medication review, and an inpatient example shows how it can be used during an endoscopy.²¹ The willingness, awareness, and widespread acceptance of the Pharmacists' Patient Care Process as the standard of care across the profession and the understanding of the process by consumers, health care practitioners, and other key stakeholders will be key to its implementation.

Standardized MTM Practice Models

MTM service development needs to be accompanied by the implementation of standardized practice models similar to those of other health care providers. This approach includes (a) implementing standardized processes for medication management to ensure consistency across patient care settings, (b) delivering care within an individual pharmacy practice through practice-developed and -documented procedures and protocols specific to the practice, (c) documenting the care provided in a patient-specific health record accessible to all providers within the practice providing care to patients, and (d) establishing a referral system in which patients identified by their physicians or other health care providers can efficiently receive their needed medication management services from a pharmacist in a coordinated and efficient manner. These practice models must be effective and efficient and have business models that support growth and expansion over time.

MTM Service Delivery Types

MTM services are delivered using a wide array of methods from face-to-face meetings to telephonic conversations to virtual video-conferencing. The MTM core elements indicate that a face-to-face delivery method is optimal because it permits a pharmacist to visually assess a patient. Although few studies exist evaluating the efficacy of MTM delivery methods (face-to-face meeting, telephonic conversation, or telehealth using video), with regard to the largest MTM payer—Medicare Part D—100% of Part D plans offer person-to-person comprehensive medication reviews (CMRs) over the phone, while 57% of the plans offer face-to-face CMRs.²²

A recent study evaluating the effect of telephonic MTM on hospital readmissions found that the lowest-risk group who received the service were three times more likely to remain out of the hospital 60 days after entering into home health care. The authors called for more study on higher-risk patients to learn if such patients needed more intense face-to-face interventions in order to achieve positive results.²³ As evidenced by this study, greater understanding of the time to apply certain methods and the intensity of service delivery is needed. This understanding needs to include patient preferences because the mode of service delivery often is dictated by the payers (plans) and may not be optimal for a patient.

MTM Barriers to Implementation

Be they real or perceived, barriers continue to exist for the implementation and integration of MTM for both providers and payers. In the APhA's 2014 *Medication Therapy Management Digest (MTM Digest)*, an environmental scan conducted by APhA since 2007, both providers and payers were surveyed on their perceived barriers to MTM services. On average, providers rated five issues as "significant" barriers: inadequate time, lack of payers paying for MTM services, low payment for MTM, difficulty in billing, and inadequate support staff.²⁴ However, those surveyed in the *MTM Digest* are likely to be providers already offering MTM services, so a wider survey of providers might find more barriers significant. One such study, published in JAPhA in 2009, surveyed 970 pharmacists in the outpatient setting on their actual and perceived barriers to providing MTM services. Although lack of payment for services was the primary barrier, 89.6% of respondents listed staffing as a barrier, and 84% listed poor access to medical information as a barrier.²⁵

Financial Sustainability

Payment for MTM services continues to be a significant barrier to sustainability and scalability in all practice settings. Medicare Part D MTM currently represents the largest covered MTM benefit, yet the majority of MTM services are delivered in-house telephonically by the PDPs, leaving a relatively small number of MTM encounter opportunities for pharmacists in outpatient settings. (According to the 2015 CMS MTM fact sheet, over 66% of programs use MTM vendor in-house pharmacists to deliver the CMR, and 28% use MTM vendor local pharmacists.) Absent a critical mass of patients, integration of MTM services into a busy practice can be difficult.²²

For pharmacists practicing in physician office practices and clinics, the primary payment option for comprehensive medication management is through physician incident-to billing, which often is not adequate to support a pharmacist. Aside from the Medicare Part D MTM benefit, several state Medicaid programs (Iowa, Minnesota, Missouri, and Ohio), and physician office practices where the physician bills for pharmacists' services, opportunities for pharmacists to provide MTM services as a covered benefit are sporadic. The profession's current provider status initiative is focused solely on achieving recognition and coverage for pharmacists' patient care services to address the critical need for payment for services.

Documentation and Billing

For those MTM services that do have associated payment, significant variability exists in documentation and billing requirements between payers that can make MTM service implementation difficult. Payers can require documentation in their own web-based platforms that sometimes contain a list of specific tasks that pharmacists must complete as part of the care. The variability between these systems and their required activities can create difficulty in delivering consistent and efficient MTM services. Pharmacists must transition between different systems depending on a patient's coverage compared to the seamless use of one system for dispensing regardless of the payer. The variability in payer requirements, including those with task-oriented activities, can make the ability to deliver care using a consistent care process challenging. Since 2008, APhA has advocated for standardized MTM documentation and billing requirements, and the formation of the Pharmacy HIT Collaborative was spearheaded because of MTM documentation and billing challenges.

Because of sufficient patient volume and the ability to document using a single electronic medical record, some practices have implemented efficient systems to document and bill for MTM services. A study at the MD Anderson Cancer Center's Ambulatory Treatment Center (where pharmacists are part of integrated care teams) over a three-month period found that difficulty with the actual billing process might be alleviated through education and awareness of resources. The study identified that "many pharmacists believed that their other duties would keep them from completing the required MTM documentation and billing." However, after provision of education and training and as experience with those tasks increased, pharmacists were more proficient at documenting and billing for services. The authors stated that they "provided further education and training using patient cases and demonstration on how to efficiently carry out the process. One-on-one training was also provided to those with continued difficulty. Even without further education, documentation and billing time decreased as pharmacists' experience increased."²⁶

In 2008, APhA passed the following policy:

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

APhA currently offers a "Billing for MTM Services" resource as does the Pharmacy HIT Collaborative, and other groups such as OutcomesMTM also offer education for using their system to document and bill for services. Currently, three time-based Current Procedural Terminology (CPT) codes approved by the American Medical Association can be used for MTM billing, if recognized by the payer. Efforts are underway through the Pharmacy HIT Collaborative to advocate for the creation of additional MTM CPT codes that better reflect the complexity of care delivered.

Patients' Engagement

Patients' understanding of and engagement in MTM services continues to be a barrier to uptake. In the 2014 APhA *MTM Digest*, payers who reimburse for MTM services found only one significant barrier to providing MTM services: "Patients are not interested or decline to participate."²⁴ This is evidenced by 2015 CMS data, which show that 67.6% of MTM programs had a CMR completion rate between 10% and 30%.³

A study published in JAPhA in 2009 reported that of 81 patients surveyed, 60% had never heard of MTM, 80% had never received a CMR, and 86% had never received a medication action plan.²⁵ A need exists to find successful methods for building awareness and engagement in MTM services. In the 2014 APhA *MTM Digest*, 75% of surveyed MTM providers and 82% of payers agreed that "direct contact with patients" was a "successful marketing strategy." The next most productive strategy was "collaboration with other health care providers" (44% of providers), followed by "word of mouth" (32% of providers).²⁴ Many pharmacists have stated anecdotally that referrals from prescribers are very effective in getting patients interested, and willing to participate, in MTM services. Further research is warranted to identify strategies for improving patient engagement in MTM services.²⁷

One survey of MTM programs recognized that more intensive MTM programs with larger time commitments correlated with decreased patient engagement.¹⁷ Given the results of the APhA *MTM Digest* surveys as well as studies citing an overall lack of awareness, additional direct pharmacist engagement with patients regarding MTM services might benefit patient engagement. CMS is also ramping up efforts to identify effective strategies for engaging patients in MTM. Factors such as increased marketing efforts, expanded patient eligibility, and education of physicians and other providers about MTM may also help increase patient engagement.

Standardization of Medication Synchronization and Appointment-Based Model

As part of an effort to implement various medication management services in community-based pharmacy practices, medication synchronization and the ABM are emerging services that have garnered interest in many sectors of the health care system. These services can enhance patient adherence, provide the convenience of a once-a-month coordinated visit to the pharmacy to pick up prescriptions, and improve efficiencies in pharmacy operations. Although the APhA Foundation, the National Alliance of State Pharmacy Associations, the National Community Pharmacists Association (NCPA), and others have performed significant work in developing models for medication synchronization and the ABM, variability remains in the marketplace in the way these programs are developed and delivered. Additionally, the inclusion of MTM services such as medication therapy reviews as part of the ABM for patients who could potentially benefit is not well defined.

Definitions of Medication Synchronization and Appointment-Based Model

The term *Appointment-Based Model* is often used synonymously with medication synchronization.⁹ However, differentiating between the two terms, and the way they are applied to improve patient adherence and pharmacy efficiencies, is important.

Medication synchronization is the process of coordinating a patient's refills for chronic medications so they are filled on the same day each month.

The ABM is a 3-part proactive process that includes the following:

- Medication synchronization to assign an appointment day each month for a patient to pick up his or her prescriptions and consult with a pharmacist
- A monthly pre-appointment call to a patient to verify the prescription order and determine if the patient is experiencing any changes or problems
- Scheduled monthly appointment where a patient picks up the prescriptions and a pharmacist consults with the patient about any ongoing experiences that might be potential issues

The APhA Foundation's white paper on the ABM states that medication synchronization is "the engine" that drives the model.²⁸ NCPA promotes a program similar to the ABM—Simplify My Meds—that contains the same steps as the ABM.²⁹

In addition to the APhA Foundation–convened consortium leading to the white paper on the ABM, the Foundation has also launched a patient awareness education initiative—Align My Refills. The focus of this education campaign is on the ability for patients to have their medication refill dates synchronized in order to reduce trips to the pharmacy and improve adherence.³⁰ This consumer-focused language is also apparent in some versions of NCPA's Simplify My Meds program. APhA and NCPA also collaborate on a map that displays those pharmacies offering ABM services.

Most studies evaluating the ABM identify two common components: (a) medication synchronization and (b) a monthly phone call to a patient. Some studies placed more emphasis on printing medication lists, identifying medications that would require partial fills given the synchronization date, and engaging a patient on fill quantity desires and feasible payment plan (single monthly payment versus interspersed payment).³¹ For achievement of comparable study results, avoidance of confusion, and improved awareness, reaching consensus on the definition and components of the appointment-based model may be advisable.

Summary

As medication management services continue to expand, the pharmacy profession must strive to implement the JCPP Pharmacists' Patient Care Process uniformly across the profession. Medication management services need to be standardized and supported by practice models that include well-developed procedures and protocols; a single system to document patient care, regardless of payer; and an established system for the effective referral of identified patients in need of medication management services from physicians to pharmacists providing these services.

Implementing Medication Synchronization and ABM

A full implementation guide and a white paper from the APhA Foundation present implementation of the medication synchronization program and ABM in 10 easy steps. However, dramatic changes in workflow and considerations of cost remain a barrier to broad implementation by some national chain pharmacies. The consortium behind the Foundation's white paper on the ABM agreed that the model requires only "minor modifications of workflow" and "emphasized that almost nothing additional is required to implement an appointment-based model." Additionally, they concluded, "the ABM is intuitive and requires almost no financial investment to be successfully implemented."³² NCPA also offers an ABM Revenue Calculator and educational videos on how to implement the ABM that may help decrease perceived or actual barriers for its implementation. Further examples and growing programs may serve to encourage organizations considering the ABM, and consideration of "potential measures" such as time spent with a consumer, pharmacist efficiency, and adherence measures may enhance support for implementation.

Research Evidence for Medication Synchronization and ABM

Numerous studies indicate good evidence that at its core, the ABM improves adherence. In a major study, the results showed “approximately 18 to 35 additional ABM study participants were adherent for every 100 patients enrolled when compared with usual care. For every 100 patients receiving usual care, 17 to 40 additional patients in the ABM study group were persistent.”³³ However, whether or not the model can yield clinical results is less clear. A study that measured patients achieving blood pressure (BP) goals through medication synchronization showed a significant decrease in overall systolic blood pressure from baseline for the medication synchronization group, but no significant difference from the study group receiving education only. Furthermore, the study was not focused solely on BP and was affected by other limitations, so “medication synchronization did not lead to a significant increase in proportion of patients at BP goal. This may indicate that further intervention is needed to impact clinical outcomes aside from ensuring that patients have their medication on hand.” However, the limitations of this study were significant, because the study did not exclude patients already at BP goal (41% in the medication synchronization group started at goal) and results were collected over a four-month period only.³⁴ Further research will help identify the benefits and value of medication synchronization and ABM.

Summary

Although implementation and adoption of medication synchronization and the ABM continue to expand in the marketplace, variability remains in the structure of the services provided. The pharmacy profession needs to further define the scope and nature of included services within the model and to define when and what types of medication management services are included and for which patients the services are most appropriate. In the environment of limited health care resources, targeting the services to those patients who have identified needs and who will receive the greatest benefit will be the most effective and efficient approach for the system as a whole. As a profession, pharmacists must strive to create a system for the ABM that appropriately identifies patients who may benefit from this model, clearly articulate what services are provided and when, and build a sustainable business model to support the broad adoption by the profession.

Conclusion

The further implementation and expansion of medication management services in pharmacy practice is a complex, multifaceted issue. Although this paper focuses on definitions and terminology and on implementation in practice, other factors to be addressed on this topic are likely to arise in the future. The pharmacy profession has specific actionable items in each of these areas to address in order to impart meaningful change in the profession and the care pharmacists are providing to patients. The creation and adoption of meaningful policy by APhA assist in moving the profession forward and help advance medication management services broadly within the health care system.

References

1. Joint Commission of Pharmacy Practitioners. Pharmacists’ patient care process. Available at: www.pharmacist.com/sites/default/files/files/PatientCareProcess.pdf. Accessed October 9, 2015.
2. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173. Available at: <https://www.congress.gov/bill/108th-congress/house-bill/1>. Accessed October 9, 2015.
3. Centers for Medicare and Medicaid Services. Medication therapy management. Available at: <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/mtm.html>. Accessed August 5, 2015.

4. Bluml BM. Definition of medication therapy management: development of professionwide consensus. *J Am Pharm Assoc*. 2005;45:566–72.
5. Medication therapy management in community pharmacy practice: core elements of an MTM service (version 1.0). *J Am Pharm Assoc* (2003). 2005;45(5):573–79.
6. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). *J Am Pharm Assoc* (2003). 2008;48(3):341–53.
7. Touchette DR, Burns AL, Bough MA, Blackburn JC. Survey of medication therapy management programs under Medicare part D. *J Am Pharm Assoc* (2003). 2006;46(6):683–91.
8. Boyd ST, Boyd LC, Zillich AJ. Medication therapy management survey of the prescription drug plans. *J Am Pharm Assoc* (2003). 2006;46(6):692–99.
9. Centers for Medicare and Medicaid Services. Medication therapy management and quality improvement program. Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter7.pdf>. Accessed October 9, 2015.
10. U.S. Department of Health and Human Services. About the law. Available at: www.hhs.gov/healthcare/about-the-law/index.html. Accessed October 9, 2015.
11. Centers for Medicare and Medicaid Services. Part D enhanced medication therapy management model fact sheet. Available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-28.html>. Accessed October 9, 2015.
12. Minnesota Department of Human Services. Minnesota Basic Health Plan Blueprint. Available at: http://mn.gov/dhs/images/exhibits_november_2014.pdf. Accessed October 9, 2015.
13. Digatono AJ. A description of medication therapy management services in Minnesota. *Innov Pharm*. 2011;2(1):34. Available at: www.pharmacy.umn.edu/innovations/prod/groups/cop/@pub/@cop/@innov/documents/article/cop_article_317765.pdf. Accessed August 15, 2015.
14. Patient-Centered Primary Care Collaborative. *The Patient-Centered Medical Home: Integrating Medication Management to Optimize Patient Outcomes*. 2nd ed. Washington, DC: Patient-Centered Primary Care Collaborative; 2012. Available at: <https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>. Accessed October 9, 2015.
15. Viswanathan M, Kahwati LC, Golin CE, et al. Medication therapy management interventions in outpatient settings. Comparative Effectiveness Review No. 138. AHRQ Publication No. 14(15)-EHC037-EF. Rockville, MD: Agency for Healthcare Research and Quality; November 2014. Available at: <http://effectivehealthcare.ahrq.gov/ehc/products/516/2002/medication-therapy-management-report-150628.pdf>. Accessed October 9, 2015.
16. Avalere Health LLC. Exploring pharmacists' role in a changing healthcare environment. May 2014. Available at: <http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>. Accessed October 9, 2015.
17. Ai AL, Carretta H, Beitsch LM, et al. Medication therapy management programs: promises and pitfalls. *J Manag Care Spec Pharm*. 2014;20(12):1162–82.
18. Accreditation Council for Pharmacy Education. ACPE topics update. Webinar, April 17, 2015. Available at: <https://www.acpe-accredit.org/pdf/Presentations/ACPEUpdateWebinar04172015.pdf>. Accessed August 15, 2015.
19. Bennett MS, Kliethermes MA, Derr S, Irwin A. APhA academies reflect on the pharmacists' patient care process of the Joint Commission of Pharmacy Practitioners. *J Am Pharm Assoc* (2003). 2015;55:230–36. doi:10.1331/JAPhA.2015.15516.
20. Bennett MS, Kliethermes MA, eds. *How to Implement the Pharmacists' Patient Care Process*. Washington, DC: American Pharmacists Association; 2015.
21. American Pharmacists Association. Pharmacists' patient care process gains traction. Available at: www.pharmacistsprovidecare.com/pharmacists-patient-care-process-gains-traction. Accessed August 20, 2015.
22. Centers for Medicare and Medicaid Services. Fact sheet: summary of 2015 MTM programs. Available at: <https://www.cms.gov/Medicare/Prescription-Drug->

Relevant APhA Policies

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.

(JAPhA NS52(4) 457 July/August 2012)

2011 *Pharmacists Role in Healthcare Reform*

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

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

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

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

Topic: Pharmaceutical Care

(JAPhA NS48(4):471 July/August 2008) (Reviewed 2010)

2003, 1992 *The Pharmacist's Role in Therapeutic Outcomes*

1. APhA affirms that achieving optimal therapeutic outcomes for each patient is a shared responsibility of the health care team.
2. APhA recognizes that a primary responsibility of the pharmacist in achieving optimal therapeutic outcomes is to take an active role in the development and implementation of a therapeutic plan and in the appropriate monitoring of each patient.

(Am Pharm NS32(6):515 June 1992) (JAPhA NS43(5):Suppl. 1:S57 September/October 2003)

(Reviewed 2007) (Reviewed 2009) (Reviewed 2010)(Reviewed 2011)

2013, 1978 *Pharmacists Providing Health Care Services*

APhA supports the study and development of new methods and procedures whereby pharmacists can increase their ability and expand their opportunities to provide health care services to patients.

(Am Pharm NS18(8):47 July 1978) (Reviewed 2007) (Reviewed 2008) (JAPhA 53(4):366 July/August 2013)



2016 House of Delegates

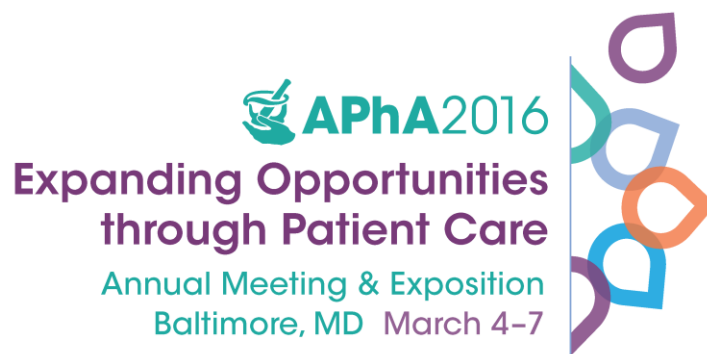
Report of the New Business Review Committee

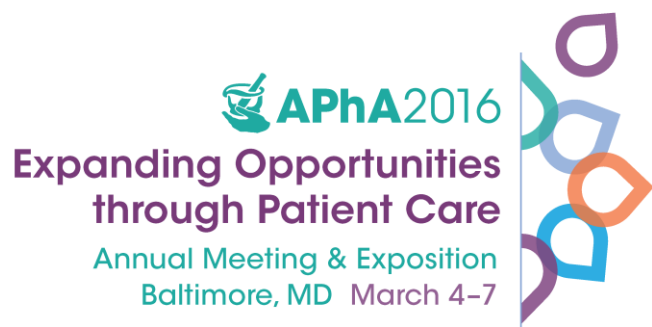
Committee Members

Heather Free, Chair
Amber Briggs
Heather Hellwig
Amy Kennedy
William T. Lee
Brenna Neumann
David Steeb
Brenna Lindsey-Swecker

Ex Officio Members

Theresa Tolle, Speaker of the House





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

Item No.: 1

Date received: 10/29/2015

Time received: 1:30 PM

**American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016**

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Brandi Hamilton, on behalf of the 2016 APhA House of Delegates Policy Review Committee
(Name)

10/29/15

(Date)

APhA Policy Review Committee

(Organization)

Subject: Drug Abuse Education

Motion: We, the members of the Policy Review Committee, urge the 2016 House of Delegates to amend the following policy statement as follows:

2003, 1987 Drug Abuse Education

APhA supports comprehensive drug abuse prevention and rehabilitation programs ~~consisting of education and rehabilitation.~~

Background:

The purpose of this amendment is to clarify intent. The original language, referring to drug abuse prevention programs, suggested that those consist of education and rehabilitation. Rehabilitation, however, comes following a failure to prevent. The new language makes the intention of APhA's support of prevention and rehabilitation clearer and more succinct.

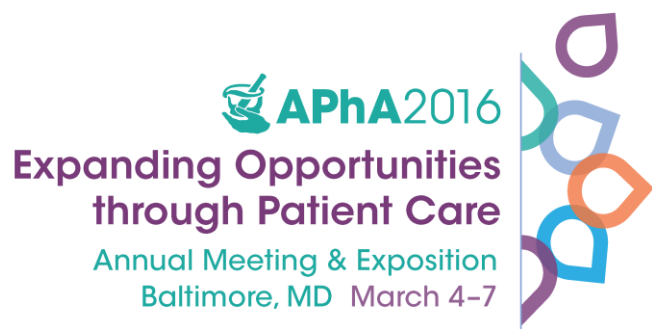
Current APhA Policy & Bylaws:

2003, 1987 Drug Abuse Education

APhA supports comprehensive drug abuse prevention programs consisting of education and rehabilitation.

(Am Pharm. NS27(6):424 June 1987) (JAPhA NS43(5): Suppl. 1:S58 September/October 2003) (Reviewed 2006)(Reviewed 2011)

New Business Items are due to the Speaker of the House by **February 3, 2016** (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.



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

Item No.: 2

Date received: 10/29/2015

Time received: 1:30 PM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Brandi Hamilton, on behalf of the 2016 APhA House of Delegates Policy Review Committee
(Name)

10/29/2015

(Date)

APhA Policy Review Committee

(Organization)

Subject: Adequacy of Directions for Use on Prescriptions and Prescription Orders

Motion: We, the members of the Policy Review Committee, urge the 2016 House of Delegates to amend the following policy statement as follows:

2011, 1995 Adequacy of Directions for Use on Prescriptions and Prescription Orders

1. APhA recommends that all professions with prescriptive authority address the issue of prescribers' responsibility for specific instructions to the pharmacist and the patient in all prescription orders, including order clarification when sought by the pharmacist.
2. APhA affirms the pharmacist's responsibility, as the patient's advocate, to obtain and communicate adequate directions for use of medications.

Background:

Pharmacists take responsibility, with reasonable consistency, for endeavoring to ensure that prescriptions/medication orders are clear and accurate. The ability to complete this task is challenged, however, when prescribers dismiss the corresponding responsibility to answer the questions and/or provide the clarification sought by the pharmacist. This jeopardizes patient care and warrants a stance by APhA.

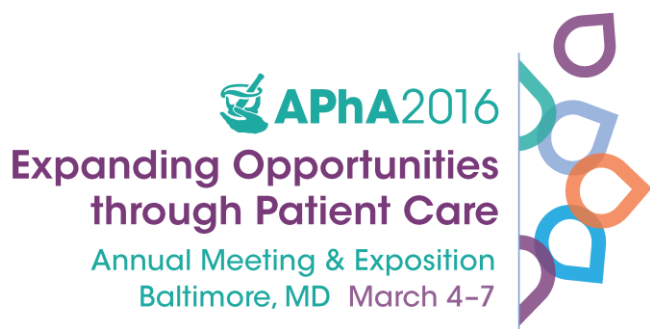
Current APhA Policy & Bylaws:

2011, 1995 Adequacy of Directions for Use on Prescriptions and Prescription Orders

1. APhA recommends that all professions with prescriptive authority address the issue of prescribers' responsibility for specific instructions to the pharmacist and the patient in all prescription orders.
2. APhA affirms the pharmacist's responsibility, as the patient's advocate, to obtain and communicate adequate directions for use of medications.

(Am Pharm NS35(6):37 June 1995) (Reviewed 2006)) (JAPhA NS51(4) 484; July/August 2011)

New Business Items are due to the Speaker of the House by **February 3, 2016** (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.



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

Item No.: 3

Date received: 11/19/2015

Time received: 9:56 AM

**American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016**

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Adriane Irwin, on behalf of the 2016 APhA House of Delegates Policy Review Committee
(Name)

11/19/15

(Date)

APhA Policy Review Committee

(Organization)

Subject: Combating Drug Abuse

Motion: We, the members of the Policy Review Committee, urge the 2016 House of Delegates to adopt the following policy statement language that updates and combines two existing policies into a single comprehensive statement. If the proposed policy is approved, then the current individual 2005 and 2006 policy statements will become archived.

1. APhA supports legislative, regulatory, and private sector efforts that include input from pharmacists to balance the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.
2. APhA supports consumer sales limits of nonprescription drug products that may be illegally converted into drugs for illicit use such as methamphetamine precursors.
3. APhA encourages education of all personnel involved in the distribution chain of nonprescription products concerning the potential for certain products, such as methamphetamine precursors, to be illegally converted into drugs for illicit use. APhA supports patient/consumer education of consequences of methamphetamine abuse.
4. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.
5. APhA supports stringent enforcement of criminal laws against individuals who engage in the trafficking of illicit drugs including methamphetamine and methamphetamine precursors.

Background:

The 2015 – 2016 Policy Review Committee reviewed the policy statements: “2006 Conversion of Nonprescription Products Into Drugs of Abuse” and “2005 Efforts to Limit Methamphetamine Access.” The committee felt there was significant overlap between the two policies and this was an opportunity to combine policy into a single comprehensive policy. Outlined below is a comparison between the existing APhA policies and with the combined policy.

2006 Conversion of Nonprescription Products Into Drugs of Abuse	2005 Efforts to Limit Methamphetamine Access	Combined Policy (Motion Above)
1. APhA supports legislative, <u>regulatory, and private sector efforts that include input from pharmacists</u> to balance the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.	1. APhA supports legislation that balances the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.	1. APhA supports legislative, regulatory, and private sector efforts that include input from pharmacists to balance the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse. Notes: This is full statement 1 from the 2006 policy.
2. APhA supports consumer sales limits of nonprescription <u>drug products that may be illegally converted into drugs for illicit use.</u>	3. APhA supports <u>retail</u> sales limits of non-prescription products that <u>contain methamphetamine precursors to prevent diversion.</u>	2. APhA supports consumer sales limits of nonprescription drug products that may be illegally converted into drugs for illicit use <u>such as methamphetamine precursors.</u> Notes: Differing verbiage was kept from 2006 policy with underlined text then added.
3. APhA <u>encourages</u> education of <u>all personnel</u> involved in the distribution chain of <u>nonprescription products concerning the potential for certain products to be illegally converted into drugs for illicit use.</u>	4. APhA <u>supports</u> education of <u>employees</u> involved in the distribution chain of <u>methamphetamine precursors about diversion, methamphetamine abuse and prevention of abuse.</u> APhA supports patient/consumer education of consequences of methamphetamine abuse.	3. APhA encourages education of all personnel involved in the distribution chain of nonprescription products concerning the potential for certain products, <u>such as methamphetamine precursors,</u> to be illegally converted into drugs for illicit use. APhA supports patient/consumer education of consequences of methamphetamine abuse. Notes: 1st Statement: Differing verbiage was kept from 2006 policy with underlined text then added. 2nd Statement: Kept from 2005 policy.

4. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.	5. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.	4. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention. Notes: There are no differences between the two policies.
	2. APhA supports stringent enforcement of criminal laws against individuals who engage in the illegal trafficking of methamphetamine and methamphetamine precursors.	5. APhA supports stringent enforcement of criminal laws against individuals who engage in the illegal trafficking of <u>illicit drugs including methamphetamine and methamphetamine precursors.</u> Notes: Policy slightly edited to make consistent with broader nature of policy.

Current APhA Policy & Bylaws:

2006 Conversion of Nonprescription Products Into Drugs of Abuse

1. APhA supports legislative, regulatory, and private sector efforts that include input from pharmacists to balance the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.
2. APhA supports consumer sales limits of nonprescription drug products that may be illegally converted into drugs for illicit use.
3. APhA encourages education of all personnel involved in the distribution chain of nonprescription products concerning the potential for certain products to be illegally converted into drugs for illicit use.
4. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.

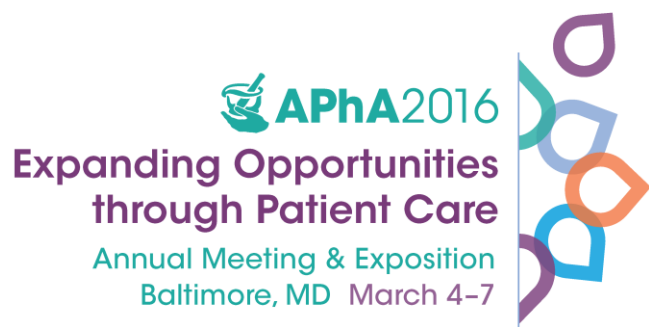
(JAPhA N46(5):561 September/October 2006)(Reviewed 2011)

2005 Efforts to Limit Methamphetamine Access

1. APhA supports legislation that balances the need for patient/consumer access to medications for legitimate medical purposes with the need to prevent diversion and abuse.
2. APhA supports stringent enforcement of criminal laws against individuals who engage in the illegal trafficking of methamphetamine and methamphetamine precursors.
3. APhA supports retail sales limits of non-prescription products that contain methamphetamine precursors to prevent diversion.
4. APhA supports education of employees involved in the distribution chain of methamphetamine precursors about diversion, methamphetamine abuse and prevention of abuse. APhA supports patient/consumer education of consequences of methamphetamine abuse.
5. APhA supports public and private initiatives that result in increased funding to address the escalating needs for drug abuse treatment and prevention.

JAPhA NS45(5):555 September/October 2005)(Reviewed 2006)(Reviewed 2011)

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

Item No.: 4

Date received: 12/8/2015

Time received 12:32 PM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Sarah Barden, on behalf of the 2016 APhA House of Delegates Policy Review Committee
(Name)

12/8/15
(Date)

APhA Policy Review Committee
(Organization)

Subject: *Legalization or Decriminalization of Illicit Drugs*

Motion: We, the members of the Policy Review Committee, urge the 2016 House of Delegates to amend the following policy statement as follows:

1990 Legalization or Decriminalization of Illicit Drugs

1. APhA opposes legalization ~~or decriminalization~~ of the possession, sale, distribution, or use of drug substances for non-medicinal uses.
2. APhA supports the use of drug courts or other evidence-based mechanisms, when appropriate as determined by the courts, to provide alternate pathways within the criminal justice system for the treatment and rehabilitation of individuals charged with illicit drug-related offenses who have substance abuse or other related medical disorders.
3. APhA supports criminal penalties for persons convicted of drug-related crimes including, but not limited to, illicit drug trafficking, drug manufacture, and drug diversion whenever alternate pathways are inappropriate as determined by the courts.

Background:

Legalization and decriminalization are two distinct concepts that should be treated independently. Opposing legalization of drug substances for non-medicinal uses (proposed statement)

1) is consistent with APhA's 1990 policy. Decriminalization means removing criminal consequences for certain actions. Since 1990, society has increased its recognition of substance abuse disorders as medical conditions that benefit from treatment and rehabilitation. As these substance abuse disorders are often the underlying cause for behaviors such as the possession

and use of drug substances for non-medicinal uses, the criminal justice system has created, piloted, and implemented “drug court” programs that allow some individuals to access treatment and rehabilitation services rather than sending them to jail.¹ These programs have been successful in helping many of these individuals, and research has shown better outcomes by treating them as patients rather than as criminals.^{2,3,4} By supporting alternative programs that help drug offenders with substance abuse disorders address their medical conditions (proposed statement)

2), APhA acknowledges and supports these new methods used to fight drug crimes developed by the criminal justice system. Supporting criminal penalties for drug-related criminal offenders when alternate pathways are inappropriate (proposed statement)

3) retains the intent of the “decriminalization” portion of the 1990 policy.

Additional References

1. Office of National Drug Control Policy. (2011). Drug Courts A Smart Approach to Criminal Justice. Retrieved December 8, 2015, from Marlowe, D. B. (2010). Research Update on Adult Drug Courts. National Association of Drug Court Professionals. Retrieved from [http://www.nadcp.org/sites/default/files/nadcp/Research Update on Adult Drug Courts - NADCP_1.pdf](http://www.nadcp.org/sites/default/files/nadcp/Research%20Update%20on%20Adult%20Drug%20Courts%20-%20NADCP_1.pdf)
2. https://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/drug_courts_fact_sheet_5-31-11.pdf
3. Rossman, S. B., et. al. (2011). The Multi-Site Adult Drug Court Evaluation: The Impact of Drug Courts. Washington, D.C. Retrieved from <https://www.ncjrs.gov/pdffiles1/nij/grants/237112.pdf>
4. Rossman, S. B., & Zweig, J. M. (2012). The Multisite Adult Drug Court Evaluation. National Association of Drug Court Professionals. Retrieved from [http://www.nadcp.org/sites/default/files/nadcp/Multisite Adult Drug Court Evaluation - NADCP.pdf](http://www.nadcp.org/sites/default/files/nadcp/Multisite%20Adult%20Drug%20Court%20Evaluation%20-%20NADCP.pdf)

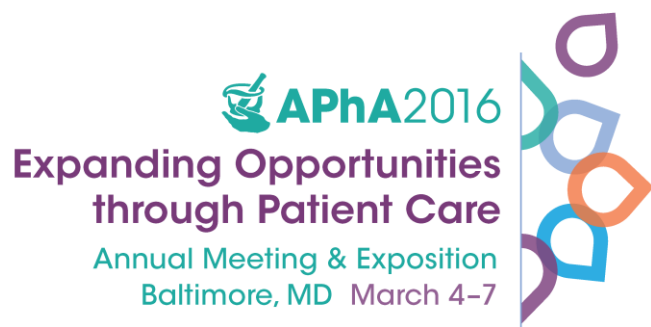
Current APhA Policy & Bylaws:

1990 Legalization or Decriminalization of Illicit Drugs

APhA opposes legalization or decriminalization of the possession, sale, distribution, or use of drug substances for non-medicinal uses.

(Am Pharm NS30(6):46 June 1990) (Reviewed 2003)(Reviewed 2006)(Reviewed 2011)

New Business Items are due to the Speaker of the House by **February 3, 2016** (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.



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

Item No.: 5

Date received: 01/20/2016

Time received: 12:10 PM

**American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016**

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Elise Barry for the New Jersey Pharmacists Association
(Name)

01/20/2016
(Date)

New Jersey Pharmacists Association
(Organization)

Subject: Generic solid dosage forms

Motion: Move to adopt the following policy statement:

APhA encourages the FDA, USP and other appropriate organizations and agencies to standardize the identification and appearance of generic solid dosage forms.

Background:

Generic bioequivalent drug substitutions have become the mainstay of cost control in the US healthcare system. Generic drugs comprise 70% of total US prescriptions and 20% of total prescription costs in 2011¹. However, generic drugs are most often differentiated from brand name products through shape, color, and size depending upon manufacturer. In the realm of mandatory generic substitutions and multiple generic manufacturers, these differences between appearances of interchangeable products can lead to patient confusion, reduced medication adherence, reduced contribution of the placebo effect and increased likelihood of prescription errors. Patients may become confused from receiving differently appearing pills upon refill of chronic medications, if the dispensing pharmacy changes manufacturers for that medication. If the patient questions the validity of differently appearing pills, the patient may wait or not even take the medication dispensed due to appearance discrepancy from previous fill, and thus leading to reduced medication adherence. Studies have shown that there is influence in therapy from the placebo effect of taking medications¹. In this scenario, a patient may not receive the equivalent therapeutic effect from a generic medication if the patient perceives the generic medication to be of lower quality/equivalence from the branded medication. Lastly, a pharmacy that frequently changes generic manufacturers may lose the ability to recognize/differentiate an appropriate product substitution based upon appearance and thus loses 1 level of verification within the dispensing process. This may increase the likelihood of a medication error occurring within the dispensing process.

A study by Kesselheim et al, Burden of changes in pill appearance for patients receiving generic cardiovascular medications after myocardial infarction: cohort and nested case-control studies, investigated the impact of proper medication use and switching between differently appearing generic equivalent substitutions from multiple manufacturers. “29% of patients had a change in pill shape, color or size during the study. A total of 4573 episodes of nonpersistence were matched to 19,881 control episodes. The odds of nonpersistence in case patients increased by 34% after a change in pill color (adjusted odds ratio, 1.34 [95% CI, 1.12 to 1.59]) and 66% after a change in pill shape (adjusted odds ratio, 1.66

[CI, 1.43 to 1.94)]².” The authors concluded that changes in appearance of generic pills are associated with reduced adherence to medication regimen. Therefore, standardization of medication adherence should help to alleviate some of the negative effects on patient adherence.

There is a legal basis to differentiation between generic and branded drug products and this is in the form of trade dress regulation. To qualify for protection under trade dress regulation, the attribute must meet 3 criteria: it must be non-functional, it must lead to confusion (or deception) if imitated and it must have a secondary association with the product for the consumer¹. In regards to pharmaceutical trade dress, functionality becomes the question and issue. In 2003, the Third Circuit Court of Appeals in *Shire v. Barr* heard the case that Barr had potentially violated trade dress by manufacturing generic Adderall in the same shape, size and color for different corresponding strengths¹. Shire’s promotions highlighted how differences in the color, size, and shape of the various doses of Adderall promoted the ability of children with ADHD to adhere to their regimens¹. The court agreed with Barr that the functionality of the color, shape and size of Adderall were not protectable under trade dress¹. This decision diminishes the legal basis for branded and generic drugs to have differing appearances.

Standardization of appearance of generic and branded medications may reduce patient confusion, increase medication adherence, promote the placebo effect in patients and reduce medication-dispensing errors. Therefore, the standardization of medication appearance serves a functional role in promoting patient safety and outcomes, and does not infringe upon trade dress protection. The NJPhA supports a shift in the pharmaceutical industry towards standardization of medication appearance between generic and branded products.

Recommendation follows an NJPhA resolution from 2002:

NEW JERSEY PHARMACISTS ASSOCIATION HOUSE OF DELEGATES ATLANTIC CITY, NEW JERSEY JUNE 19, 2002

RESOLUTION NUMBER 4

Subject: Standardization for Identification and Appearance of Generic Solid Dosage Forms

Motion: NJPHA encourages the FDA, USP and other appropriate organizations and agencies to standardize the identification and appearance of generic solid dosage forms where multiple strengths are available.

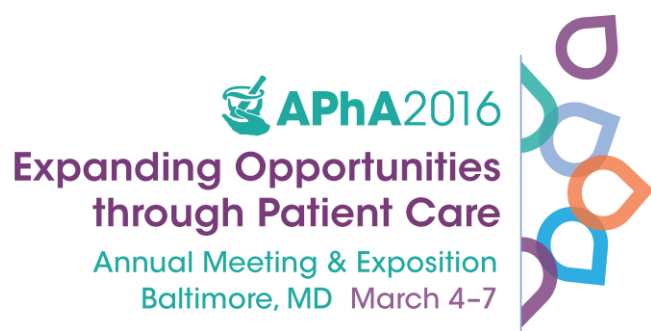
References:

- 1) Greene J, Kesselheim A. Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health. *N Engl J Med* 2011; 365:83-89 July 7, 2011 DOI: 10.1056/NEJMhle1101722
- 2) Kesselheim S, Bykov K, Avorn J, et al. Burden of changes in pill appearance for patients receiving generic cardiovascular medications after myocardial infarction: cohort and nested case-control studies. *Ann Intern Med*. 2014 Jul 15;161(2):96-103. doi: 10.7326/M13-2381.
- 3) [Annals of Internal Medicine article](http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/175/original_policy_proposal_article-annuals_of_internal_medicine-pill_appearance.pdf): http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/175/original_policy_proposal_article-annuals_of_internal_medicine-pill_appearance.pdf
- 4) [New England Journal of Medicine article](http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/181/original_nejmhle1101722.pdf): http://s3.amazonaws.com/njphasite-dev/ckeditor_assets/pictures/181/original_nejmhle1101722.pdf

Current APhA Policy & Bylaws:

No current policy exists.

New Business Items are due to the Speaker of the House by **February 3, 2016** (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.



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

Item No.: 6
Date received: 01/21/2016
Time received: 12:10 PM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Elise Barry for the New Jersey Pharmacists Association
(Name)

01/21/16
(Date)

New Jersey Pharmacists Association
(Organization)

Subject: Biotechnology

Motion: Move to adopt the following policy statement:

APhA supports legislation or regulation that requires all phases of clinical data on biosimilar and small molecule generics to be made available on clinicaltrials.gov and published in peer reviewed and retrievable literature.

Background:

Biologics are complex, biotechnology-derived drugs that originate from living sources. These biologics are often difficult to replicate due to their complex nature. "A biosimilar product is a biological product that is approved based on a showing that it is highly similar to a Food and Drug Administration (FDA) approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.¹" It is also important to note that biosimilars may not carry all of the indications that the reference biologic does. Biologics differ from small molecule drugs in size and complexity. Generic versions of small molecule drugs are identical in structure to the reference drug, whereas biosimilars are not identical in structure to reference products.

An interchangeable product is biosimilar to a reference product and can be expected to produce the same clinical effect as the reference product.¹ Interchangeable products may be substituted at the pharmacy if the FDA has determined the product interchangeable and the appropriate state law allows such rights to the pharmacist. The topic of interchangeability and substitution is left to state pharmacy laws regarding biosimilars. "FDA must find a biosimilar to be interchangeable with its reference product if the information submitted by the biosimilar applicant demonstrates that: The applicant's product is biosimilar to the reference product (under the law's standard for biosimilarity) The applicant's product can be expected to produce the same clinical result as the reference product in any given patient.²"

Access to clinical trial data in regards to biosimilars and interchangeable products would be imperative in formulating these substitution decisions.

Clinicaltrials.gov is one of the largest public registries for clinical research studies. It was established in 2009 in order for clinical trials to publish their basic results. It allows public access to data including participants and their characteristics, overall limitations, outcome measures, adverse events, and more. The results summary is made available no later than 1 year after the trial completion date.

It is important for health care providers to have access to biosimilar clinical trials for a variety of reasons. “The “Purple Book” lists biological products, including any biosimilar and interchangeable biological products licensed by FDA under the Public Health Service Act (PHS). The lists include the date a biological product was licensed under the PHS Act and whether FDA evaluated the biological product to the reference product. The Purple Book will also enable a user to see whether a biological product licensed has been determined by FDA to be biosimilar to or interchangeable with a reference biological product. Biosimilar and interchangeable biological products licensed under the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.”³ If the information needed is not provided within the purple book, pharmacists and other health care providers need a reliable resource. The information on biosimilar safety, efficacy, pharmacokinetic, and pharmacodynamic data contained in clinical trials can be advantageous in the decisions regarding interchanging products. It is inappropriate to assume similar adverse events with biosimilars and their reference product as you may have been able to with small molecule drugs and their generics.

The significance in obtaining clinical trial data for biosimilars is the concern in efficacy and safety in the products dependent on small changes in the development. “Examples of changes include alterations in the product’s isoforms, three-dimensional protein structure, quantity of acid-base variants, and glycosylation profile. Changes such as these, which often are due to variability in source materials, cell line used, extraction and purification processes, and scale changes, may result in alterations in clinical efficacy and safety.”⁴ Since biosimilars are not identical to the reference product, more information is needed on their efficacy, safety, and overall clinical trial data.

Currently, Section 801 of the Food and Drug Administration Amendments Act mandates the registration with ClinicalTrials.gov of certain clinical trials including those of biological products.⁶ Transparency of clinical trials and registry to clinicaltrials.gov is important because it allows others to determine whether the study is appropriate according to their concern, if the integrity of the trial was maintained based on their protocol, and it allows efficient allocation of resources. Therefore, it would be appropriate to include biosimilar clinical trial data onto clinicaltrials.gov database.

References

1. “Biosimilars” *U.S. Food and Drug Administration*. 2015
2. Bogaert, P., Lietzan, E., Sim, L. “Biosimilar Regulation: Important Considerations and Global Developments” *Life Sciences Handbook*. 2011
3. “Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations” *U.S. Food and Drug Administration*.
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>. Accessed 01/21/2016.
4. Alten, R., Cronstein, B. “Clinical Trial Development for Biosimilars” *Seminars in Arthritis and Rheumatism*. 2015; 44 (52-58).
5. “Information on Registering and Reporting Results of Clinical Trials” *Protocol Registration and Results System*.
<https://prsinfo.clinicaltrials.gov/>. Accessed 01/09/2016.
6. “Understanding Key Differences Between Biosimilars and Small Molecule Generics” *Pharmacy Practice News*. 2013.
7. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>

Current APhA Policy & Bylaws:

2012, 2007 Biologic Drug Products

1. APhA encourages the development of safe, effective, and affordable therapeutically equivalent generic/biosimilar versions of biologic drug products, including clinical trials that assess safety.
2. APhA encourages the FDA to develop a scientifically based process to approve therapeutically equivalent generic/biosimilar versions of biologic drug products.
3. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.
4. APhA should initiate educational programs for pharmacists and other health care professionals concerning the determination of therapeutic equivalence of generic/biosimilar versions of biologic drugs products.

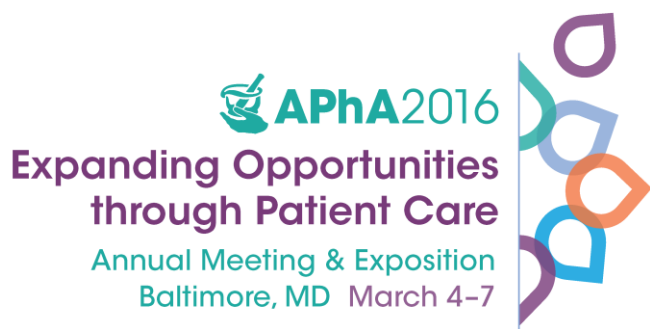
(JAPhA NS45 (5):580 September-October 2007)) (JAPhA NS52(4) 458 July/August 2012)

2005 Public Access to Clinical Trials Data

APhA supports access by healthcare professionals and the public to all clinical trial data derived from scientifically valid studies. APhA supports the establishment of a single, independent, publicly accessible clinical trials database that includes but is not limited to the following components: (a) includes all studies, pre and post drug approval, throughout the research period (whether completed, in-progress or discontinued) (b) clearly states the size, demographics, limitations and citations, if published, of each study listed (c) includes an interpretative statement by an independent review body regarding the purpose of the study, methodology and outcomes to assist the public in understanding the posted information in a timely manner (d) includes warnings to the public regarding inappropriate or incomplete use of the data in making clinical decisions in absence of an interpretive statement (e) the sponsor and any supporting company, organization, or partnered institution of each clinical trial listed shall be clearly identified. (This includes Clinical Research Organizations, Academic Research Organizations, Site Management Organizations or any other group that is responsible other than the investigator's research site.)

(JAPhA NS45(5):554-555 September/October 2005) (Reviewed 2009)(Reviewed 2014)

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

Item No.: 7

Date received: 01/26/2016

Time received: 7:21 AM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: _____ Daniel Hussar _____

1/26/16

(Date)

Pennsylvania Pharmacists Association

(Organization)

Subject: Food and Drug Administration (FDA) Authorization for Selected Medications/Dosage Forms to be Available Without a Prescription from a Pharmacist

Motion: Move to adopt the following policy statement language:

APhA urges the FDA to authorize the following medications/dosage forms to be available without a prescription from a pharmacist:

- Naloxone for opioid over dosage
- Epinephrine auto-injectors for severe allergic reactions
- Albuterol for oral inhalation for acute asthma attacks
- Nitroglycerin for sublingual use for symptoms of a heart attack
- Varenicline for smoking cessation
- Nicotine nasal spray for smoking cessation
- Nicotine inhalation system for smoking cessation

Background:

The epidemic of abuse of opioids and the tragedies of deaths from over dosage warrant the most timely availability and use of naloxone. Naloxone is a life-saving intervention but it must be administered as soon as possible following over dosage. On a state-by-state basis pharmacists and others (e.g., police) are being provided the authority to provide and/or use naloxone without a prescription. However, for states to address this matter on an individual basis is a grossly inefficient waste of time, effort, and resources when the FDA is in a position to authorize on a national basis the availability of naloxone without a prescription from a pharmacist.

Similarly, epinephrine, albuterol, and nitroglycerin can be life-saving interventions for urgent medical problems that require immediate availability and use. Pharmacists are the most accessible healthcare professionals and can also provide the needed medications on a timely basis.

The problems resulting from smoking cigarettes are contributing factors to the deaths of more than 440,000 individuals each year in the United States, and represent the country's most important public health challenge. There is an unacceptable irony that cigarettes with their multiple toxins can be purchased by only providing proof of age while there are restrictions (e.g., the need for a prescription) on the availability of products that will help people stop smoking. The risks and consequences of smoking far exceed any risks associated with the use of varenicline, nicotine nasal spray and nicotine inhalation system, and these products should be available without a prescription from a pharmacist.

Current APhA Policy & Bylaws:

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

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.
2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.
4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

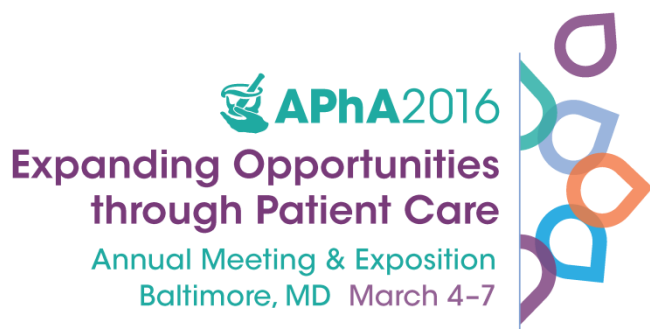
(JAPhA 54(4) July/August 2014)(Reviewed 2015)

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.

(JAPhA NS11:270 May 1971) (JAPhA NS45(5):555 September/October 2005) (Reviewed 2009)(Reviewed 2014)

New Business Items are due to the Speaker of the House by **February 3, 2016** (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.



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

No. : 8

Date received: 2/2/2016

Time received: 5:00 PM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Maj Richard Caballero, USAF
(Name)

2/2/2016
(Date)

Federal Delegation
(Organization)

Subject: Drug Disposal

Motion: Move to adopt the following policy statement:

APhA encourages increasing the percentage of available pharmacies that register as collection sites to expand patient access to disposal locations in a secure, convenient, and responsible manner in accordance with the Disposal Act.

Background:

The National Survey of Drug Use and Health 2010 data has concluded that friends and family are the primary sources of abused opioids. This study reported 55% of persons who reported non-medical use of pain relievers obtained their supply from a family member or friend. The Drug Enforcement Agency has hosted biannual Drug Take-Back events with spurious success. The Drug Disposal Act of 2010 amended the Controlled Substance Act to allow a subset of DEA pharmacy registrants to register as authorized collection sites to increase access to secure and convenient disposal locations. Several states have already passed legislation to allow pharmacies to register as collectors of controlled substances; however, some states have not. APhA is in a position to endorse the wide adoption of standardized state-wide legislation as well as advocate for pharmacies to develop responsible disposal programs aimed at increasing patient access to such services. **Law has changed (current policy is obsolete) and APhA position can serve an advocacy role.**

Current APhA Policy & Bylaws:

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.
2. APhA encourages provision of patient-appropriate quantities of medication supplies to minimize unused medications and unnecessary medication disposal.

(JAPhA NS49(4):493 July/August 2009)(Reviewed 2012)(Reviewed 2013)

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.

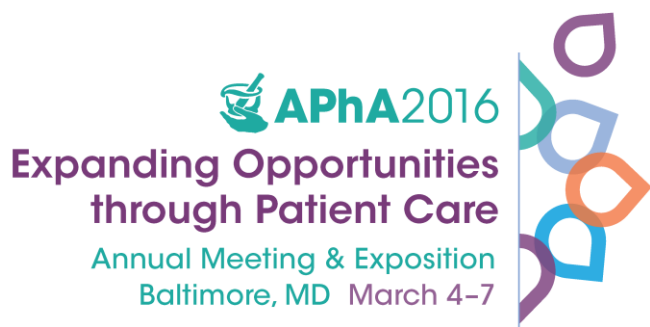
(JAPhA 53(4): 365 July/August 2013)

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.

(Am Pharm NS30(6):45 June 1990) (Reviewed 2004) (Reviewed 2007)(Reviewed 2012)

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

Item No.: 9

Date received: 02/2/2016

Time received: 5:18 PM

**American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016**

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: CDR Irene Ahlstrom (USPHS)
(Name)

2/2/16
(Date)

Federal Delegation
(Organization)

Subject: Medication Assisted Treatment

Motion: Move to adopt the following policy statements:

1. APhA supports pharmacists expanding access to Medication Assisted Treatment (MAT) by establishing Pharmacist based Injection Services for opioid abuse treatment/maintenance based on a valid prescription.
2. APhA supports pharmacists creating a system of care working in collaboration with the physician, behavioral health counselors and other health care providers to provide integrated patient centered care.

Background:

Drug overdose was the leading cause of injury death in 2013. Among people 25 to 64 years old, drug overdose caused more deaths than motor vehicle traffic crashes. According to the Centers for Disease Control and Prevention (CDC), the number of overdose deaths involving prescription opioids quadrupled between 1999 and 2013, with more than 16,000 deaths in 2013. Overdose deaths involving heroin have sharply increased, nearly doubling between 2011 and 2013. Drug overdose was the leading cause of accidental death in the US, with 47,055 lethal drug overdoses in 2014. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

Medication Assisted Treatment (MAT) is the combination of medications along with counseling and behavioral therapies to treat substance use disorders and prevent overdose. MAT is used to effectively treat and maintain abstinence to prevent overdose. The ultimate goal of MAT is full recovery. Unfortunately, MAT is underused, partially due to lack of access and knowledge along with the saturation of existing treatment capacity. Pharmacist participation would help to increase access and awareness.

"Drug Overdose Deaths by State, US 2013 and 2014." *Drug Overdose Deaths by State, US 2013 and 2014 / Prescription Drug Overdose / CDC Injury Center*. The Centers for Disease Control and Prevention (CDC), 18 Dec. 2015. Web. 22 Jan. 2016.

"Fatal Injury Data." *Fatal Injury Data / WISQARS / Injury Center / CDC*. The Centers for Disease Control and Prevention (CDC), 13 July 2015. Web. 22 Jan. 2016.

"Presidential Memorandum - - Addressing Prescription Drug Abuse and Heroin Use. *Presidential Memorandum - - Addressing Prescription Drug Abuse and Heroin Use / whitehouse.gov*. The WHITE HOUSE, 21 Oct. 2015. Web. 22 Jan. 2016.

"Medication and Counseling Treatment." *Medication and Counseling Treatment / SAMHSA*. Substance Abuse and Mental Health Service Administration (SAMHSA), 28 Sep. 2015. Web. 22 Jan. 2016.

"Pharmacist guide to medication-assisted treatment of substance abuse." *Pharmacist guide to medication-assisted treatment of substance abuse / American Pharmacists Association*. American Pharmacists Association® (APhA), 1 Nov. 2015. Web. 22 Jan. 2016.

Jones, Christopher M., Melinda Campopiano, Grant Baldwin, and Elinore McCance-Katz.

"National and State Treatment need and Capacity for Opioid Agonist Medication-Assisted Treatment." *American Journal of Public Health* 105.8 (2015): e55-63. Web. 22 Jan. 2016.

"Opioid Addiction 2016 Facts and Figures." American Society of Addiction Medicine (ASAM), n.d. Web. 22 Jan. 2016.

"Deaths from Prescription Opioid Overdose." *Prescription Drug Overdose Data / Prescription Drug Overdose / CDC Injury Center*. The Centers for Disease Control and Prevention (CDC), 16 Oct. 2015. Web. 22 Jan. 2016.

Current APhA Policy & Bylaws:

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

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.
2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.
4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA 54(4) July/August 2014)(Reviewed 2015)

2003 Drug Addiction/Chemical Dependency Education

APhA urges pharmacists and pharmacy students to become educated in the recognition and treatment of drug addiction and chemical dependency.

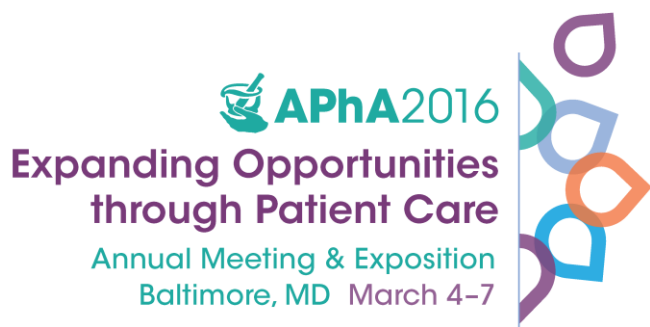
(JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2006)(Reviewed 2011)

2003, 1983 The Use of Controlled Substances in the Treatment of Intractable Pain

1. APhA supports the continued classification of heroin as a Schedule I controlled substance.
2. APhA supports research by qualified investigators under the Investigational New Drug (IND) process to explore the potential medicinal uses of Schedule I controlled substances and their analogues.
3. APhA supports comprehensive education to maximize the proper use of approved analgesic drugs for treating patients with chronic pain.
4. APhA recognizes that pharmacists receiving controlled substance prescription orders used for analgesia have a responsibility to ensure that the medication has been prescribed for a legitimate medical use and that patients achieve the intended therapeutic outcomes.
5. APhA advocates that pharmacists play an important role on the patient care team providing pain control and management.

(Am Pharm NS23(6):52 June 1983)(JAPhA NS43(5):Suppl. 1:S58 September/October 2003)(Reviewed 2006)(Reviewed 2011)(Reviewed 2012)(Reviewed 2013)(Reviewed 2015)

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

Item No.: 10
Date received: 2/3/2016
Time received: 3:48 PM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Jeffrey Bratberg, PharmD, BCPS
(Name)

2/3/16
(Date)

Individual Delegate of APhA-APPM
(Organization)

Subject: *Opioid Overdose Prevention*

Motion: To adopt new policy statements that will complement current APhA Policy.

1. APhA supports access to, coverage of, and payment for third-party/caregiver prescription and dispensing of opioid reversal agents, issued as a prescription, or by standing order, collaborative practice agreement, or other legal or regulatory mechanism to increase opioid reversal agent distribution via pharmacists.
2. APhA affirms that third-party prescriptions are issued for legitimate medical purposes and should be reimbursed by public and private payers for members who seek to protect their communities, friends, and family members exactly as prescriptions issued to members with risk factors for opioid overdose.

Background:

As the most accessible healthcare professionals and medication safety experts in the community, pharmacists frequently encounter caregivers, family, and friends of patients (“third parties”) at the highest risks of opioid overdose, patients who use heroin and/or prescription opioids. Since most opioid overdoses are witnessed, it’s essential that pharmacists present the fewest barriers to people in a position to respond using opioid overdose reversal agents, principally naloxone.

As of September 2015, clinicians with prescribing authority in 38 states are permitted to prescribe naloxone to third-parties, legally waiving the requirement of a relationship between the prescriber and the person who will ultimately receive the drug. The policy language clearly defines the legal end-user, or the person whose name appears on the prescription, as either the person at risk of overdose themselves, or a person in a position to help someone at risk of overdose (and/or a friend, family member, or caregiver). **These prescriptions are further defined as being written for someone with a legitimate medical need.**

In at least 40 states, pharmacists can also prescribe naloxone through standing orders, collaborative practice agreements, and/or independent prescriptive authority. No matter the prescription mechanism, the third party

prescription of an opioid reversal agent is interpreted exactly as a prescription for someone with risk factors for overdose, and is for a legitimate medical need as specified in statute and/or regulation.

Since the opioid reversal agent is being dispensed to a person who may not be using the medication on themselves, and may be administered to an individual who is not covered by that person's insurance, pharmacists, pharmacy-benefit managers, insurers, and others have expressed concerns that this practice violates contract language or even constitutes fraud.

As a result, some pharmacies and providers are appropriately apprehensive of legal consequences and/or insurer audits, and have restricted third-party access to naloxone to only those who can pay the cash price for a naloxone kit.

In the interest of public health, APhA should support continued and expanded access to opioid reversal agents to sustain caregiver naloxone access through federal, state, and private insurer coverage and payment.

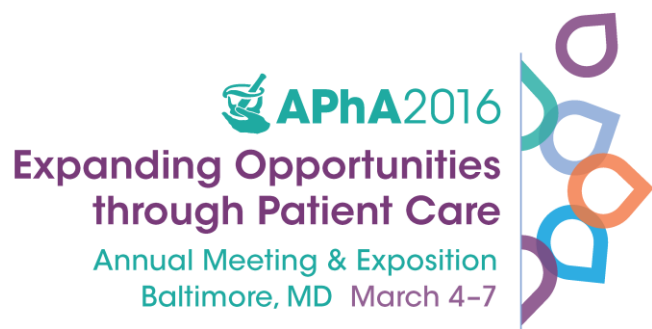
Current APhA Policy & Bylaws:

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

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.
2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.
4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA 54(4) July/August 2014)(Reviewed 2015)

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

Item No.: 11

Date received: 2/3/2016

Time received: 4:21 PM

American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Lucianne West on behalf on APhA-ASP; Nicki Hilliard on behalf of APhA-APPM

(Name)

02/03/2016

(Date)

APhA-ASP and APhA-APPM

(Organization)

Subject: Labeling and Measurement of Oral Liquid Medications

Motion: Move to adopt the following policy statements,

1. APhA supports the use of the milliliter (mL) as the standard unit of measure for oral liquid medications.
2. APhA encourages the mandatory use of leading zeros before the decimal point for amounts less than one on prescription container labels for oral liquid medications.
3. APhA discourages the use trailing zeros after the decimal point for amounts greater than one on prescription container labels for oral liquid medications.
4. APhA supports access to and universal availability of dosing devices with numeric graduations that correspond to the unit of measure on the container labeling for oral liquid medications.

Background:

Between 2002 and 2012, 81.9% of medication errors involving children six and younger were attributed to liquid medications. The second and third most common causes of these medication errors were incorrect dose and confused unit of measure, respectively.¹ Sobhani et al. compared the use of dosing cups and syringes to measure a dose of an over the counter (OTC) product. The investigators concluded that no participants measured an excessive dose while using the syringe. Alternatively, 85.4% of participants using a dosing cup measured an excessive dose.²

The Centers for Disease Control (CDC) recently launched the PROTECT initiative to address the alarming increase in emergency room visits due to OTC and prescription medication overdoses in children. The initiative focused on promoting safe medication packing with clearer dosing measures and labeling to ensure ease of administration by caregivers and increased education for parents and caregivers about proper use and administration of OTC medications.³

The National Council for Prescription Drug Programs' white paper describes the measures relating to the standardization of dosing designations by which these parties can play that role. The document addresses the necessary standardization of oral liquid medication container labels and the dosing devices commonly used with OTC liquid medications. The recommendations include packaging a precision measuring device with OTC oral liquid medications. The recommendations also include the adoption of milliliters as the standard unit of measure for such products.⁴

The standardization of all units of measure to milliliters would decrease dosing and measurement confusion. Teaspoons have been shown to range anywhere from 2.5 to 7.8 milliliters. Furthermore, production inconsistencies are common in measurement devices intended for cooking.⁵

Patient education has also been shown to significantly improve dosing accuracy in liquid oral medications. McMahon et al. found that 83% of patients that used a dosing syringe without a demonstration could dose a medication accurately, while 100% of participants who received a demonstration dosed the medication accurately.⁶

Yin et al. demonstrated that advanced counseling techniques with the provision of a precision measuring device is shown to be more effective (47.8% measured an accurate dose) than those who received neither (20.9% measured an accurate dose).⁷ The provision of a precision measuring device and patient education and the standardization of units are synergistic in combination and beneficial to patient safety and quality of care.

References:

1. Smith, MD, et al. Out-of-Hospital Medication Errors Among Young Children in the United States, 2002-2012. *Pediatrics*. 2014; 134,5:867-876.
2. Sobhani, P, et al. Accuracy of Oral Liquid Measuring Devices: Comparison of Dosing Cup and Oral Dosing Syringe. *The Annals of Pharmacotherapy*. 2008;42:46-52
3. The PROTECT Initiative: Advancing Children's Medication Safety. Centers for Disease Control. Accessed at: http://www.cdc.gov/medicationsafety/protect/protect_initiative.html. January 31, 2016.
4. NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications. Accessed at: <http://ncdp.org/Education/Whitepaper>. January 31, 2016.
5. Yaffe, SJ, et al. Inaccuracies in Adminstrating Liquid Medication. *Journal of the American Academy of Pediatrics*. 1975; 56:327
6. McMahon SR, et al. Parents can dose liquid medications accurately. *Pediatrics*. 1997; 100:300-3
7. Yin, SH, et al. Liquid Medication Dosing Errors in Children: Role of Provider Counseling Strategies. *Academic Pediatrics*. 2014; 14,3:262-270

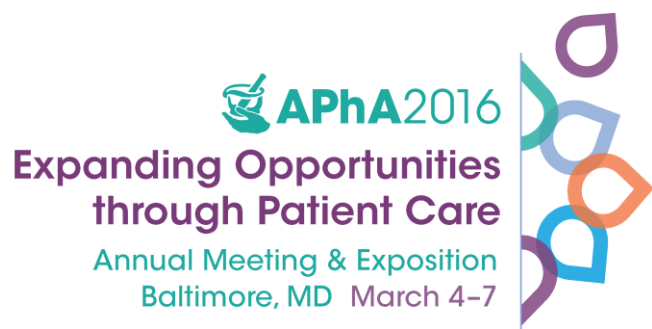
Current APhA Policy & Bylaws:

No current APhA Policy. However, the 2015 APhA-ASP House of Delegates adopted the following resolutions:

2015.2 – Labeling and Measurement of Oral Liquid Medications

1. APhA-ASP supports mandatory inclusion of a precision measuring device, such as an oral syringe, with all prescription and non-prescription oral liquid medications.
2. APhA-ASP encourages student pharmacists and pharmacists to educate patients and caregivers on accurate oral liquid medication administration.
3. APhA-ASP supports the use of metric units (versus teaspoons and tablespoons) as the standard measurement on all oral liquid medications and precision measuring devices.

New Business Items are due to the Speaker of the House by **February 3, 2016** (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.



**American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016**

**To be completed by the Office of the
Secretary of the House of Delegates**

Item No. _____

Date received _____

Time received _____

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: _____
(Name)

(Date)

(Annual Meeting Contact Number)

(Organization)

Subject:

Motion:

Background:

Current APhA Policy & Bylaws:

****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 3, 2016** (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.