

House of Delegates Session—2020

June 7 and 9, 2020 Online Meetings

Proceedings of the 72nd annual session of the ASHP House of Delegates,
June 7 and 9, 2020

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Paul W. Abramowitz, Secretary

The 72nd annual session of the ASHP House of Delegates was held online due to the cancellation of the 2020 ASHP Summer Meetings in response to the COVID-19 pandemic.

First meeting

The first meeting was convened at 1:00 p.m. Sunday, June 7, by Chair of the House of Delegates Casey H. White. Chair White welcomed delegates and then introduced Kathleen S. Pawlicki, President of ASHP and Chair of the of Directors, to announce that the ASHP Board of Directors had approved the creation of an ASHP Task Force on Racial Diversity, Equity, and Inclusion. The House observed 8 minutes and 46 seconds of silence in memory of George Floyd, Ahmed Aubrey, Breonna Taylor, and countless other Black Americans whose tragic and senseless deaths inspired protests for social justice and equity around the world.

Chair White then described the purposes and functions of the House. He emphasized that the House has considerable responsibility for establishing policy related to ASHP professional pursuits and pharmacy practice in hospitals and health systems. He reviewed the general procedures and processes of the House of Delegates.

The roll of official delegates was called during the online sign-in process. A quorum was present, including 206 delegates representing 50 states and the District of Columbia (no delegates from Puerto Rico), as well as the federal services, chairs of ASHP sections and forums, ASHP officers, members of the Board of Directors, and ASHP past presidents (see Appendix I for a complete roster of delegates).

Chair White reminded delegates that the report of the 71st annual session of the ASHP House of Delegates had been published on the ASHP website and had been distributed to all delegates. Delegates had been advised earlier to review this report. The proceedings of the 71st House of Delegates session were received without objection.

Report of the Committee on Nominations.

Chair White directed the delegates' attention to the report of the Committee on Nominations (Appendix II).^a Nominees in the report were as follows:

President 2021-2022

Lea S. Eiland, Pharm.D., BCPPS, BCPS, FASHP, FPPA, Clinical Professor and Associate Department Head, Auburn University, Auburn, AL

Linda S. Tyler, Pharm.D., FASHP, Chief Pharmacy Officer, University of Utah Health, Salt Lake City, UT

Board of Directors, 2021-2024 Kim W. Benner, Pharm.D., BCPS, FASHP, FPPA, Professor of Pharmacy Practice, Samford University McWhorter School of Pharmacy, Homewood, AL

Dan Degnan, Pharm.D., M.S., CPPS, FASHP, Associate Director, Professional Program Laboratory, Clinical Assistant Professor of Pharmacy Practice (Courtesy),

Purdue University College of Pharmacy, West Lafayette, IN

Neil J. MacKinnon, B.S.Pharm., Ph.D., M.S., FCSHP, FNAP, Dean and Professor, University of Cincinnati, Cincinnati, OH

Pamela K. Phelps, Pharm.D., FASHP, FMSHP, Pharmacy Director, M Health Fairview, Minneapolis, MN

Chair White announced that a virtual "Meet the Candidates" session will be recorded and made available to members via podcasts on the ASHP website.

Policy committee reports. Chair White outlined the process used to generate policy committee reports (Appendix III). He announced that he would introduce the recommended policies from each council consecutively. He further advised the House that any delegate could raise questions and request discussion by asking to be recognized.

Chair White also announced that delegates could suggest minor wording changes (without introducing a formal amendment) that did not affect the substance of a policy proposal, and that the Board of Directors would consider these suggestions and report its decisions on them at the second meeting of the House.

(Note: The following reports on House action on policy committee recommendations give the language adopted at the first meeting of the House. The titles of policies amended by the House are preceded by an asterisk [*]. Amendments are noted as follows: underlined type indicates material added; strikethrough marks indicate material deleted. If no amendments are noted, the policy as proposed was adopted by the House. For purposes of this report, no distinction has been made between formal amendments and wording suggestions made by delegates.

The ASHP Bylaws [Section 7.3.1.1] require the Board of Directors to reconsider an amended policy before it becomes final. The Board reported the results of its "due consideration" of amended policies during the second meeting of the House; the double underlined type indicates material added during the Board's due consideration and the double strikethrough marks indicate material deleted by the Board.)

Policy recommendations 1 through 5 from the **Council on Public Policy** were presented.

1. Access to Affordable Healthcare

To advocate for access to affordable healthcare for all residents of the United States, including coverage of medications and related pharmacist patient care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment outcomes; (3) minimize overall costs without compromising quality; and (4) ensure patient choice of healthcare providers, including pharmacy services; further,

To advocate that healthcare payers seek to optimize continuity of care in their design of benefit plans.

Note: This policy would supersede ASHP policy 1001.

2. Care Commensurate Reimbursement

To advocate that reimbursement for healthcare services be commensurate with the level of care provided, based on the needs of the patient.

3. Funding, Expertise, and Oversight of State Boards of Pharmacy

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians; further,

To advocate that <u>hospitals and</u> health systems are adequately represented on state boards of pharmacy; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,

To advocate that inspections be performed only by pharmacists competent about individuals with demonstrated competency in the applicable area of practice.

Note: This policy would supersede ASHP policy 1507.

4. Dispensing by Nonpharmacists and Nonprescribers

To reaffirm the position that to ensure optimal patient outcomes all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,

To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient protection and safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing, regardless of setting, be held to the same regulatory standards that apply to dispensing by a pharmacist; further,

To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

Note: This policy would supersede ASHP policy 0010.

5. New Categories of Licensed Pharmacy Personnel

To oppose the creation of new categories of licensed pharmacy personnel.

Policy recommendations 1 through 3 from the **Council on Therapeutics** were presented.

1. Safety and Efficacy of Compounded Topical Formulations

To encourage pharmacists to take a leadership role in developing advocate for the development of processes that would ensure potency, quality, safety, and effectiveness and standardization of compounded topical formulations; further,

To advocate that public and private entities establish a process to evaluate and regulate the safety, efficacy, and composition of compounded topical formulations; further,

To advocate that ASHP expand its repository of evidence-based formulations that could serve as a resource for compounding topical formulations; further,

To advocate that public and private payers and healthcare providers collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the prescribing and use of compounded topical formulations; further,

To encourage pharmacists to take a leadership role in developing and providing education on the safety and efficacy of compounded topical formulations to providers and consumers.

2. Postmarketing Studies

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA and other agencies to fulfill this expanded mission related to postmarketing surveillance and studies; further, To advocate that such studies compare a particular approved drug product or licensed biologic product with (as appropriate) other approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

To advocate expansion of studies of approved drug products or licensed biologic products to improve safety and therapeutic outcomes and promote cost-effective use; further,

To encourage impartial <u>public-private</u> <u>partnerships or private-sector entities to also conduct such studies.</u>

Note: This policy would supersede ASHP policies 1004 and 0515.

3. Gabapentin as a Controlled Substance

To advocate that the Drug Enforcement Administration <u>classify</u> reschedule gabapentin to <u>as a Schedule V substance</u> due to its low potential for abuse and patient harm.

The policy recommendation from the Council on Education and Workforce Development was presented.

1. Residency Training for Pharmacists Who Provide Direct Patient Care

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that experience; further,

Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position that the completion of an ASHP-accredited postgraduate-year-one residency be required for all new college or school of pharmacy graduates who will be providing direct patient care.

Note: This policy would supersede ASHP policies 0701 and 0005.

Policy recommendations 1 through 7 from the **Council on Pharmacy Management** were presented.

1. Pharmacist's Role in Health Insurance Benefit Design

To advocate that pharmacy practice leaders collaborate with internal and external partners who design, negotiate, and select their own organization's health plans and pharmacy benefit management contracts to preserve patient continuity of care and the integrity of the health-system pharmacy operations. enterprise; further,

To provide education and resources for all partners on the health plan development process, analysis of pharmacy benefit design, contemporary formulary review processes, and application of medication safety principles on formulary decision-making.

*2. Preserving Patient Access to Pharmacy Services by Medically Underserved Populations

To advocate for funding and innovative payment models to preserve patient access to acute and ambulatory care pharmacy services **in by** rural **and or** medically underserved populations areas; further,

To support the use of telepharmacy telehealth to maintain pharmacy operations and pharmacist-led comprehensive medication management that extend patient care services to and enhance continuity of care in for rural and or medically underserved populations areas; further,

To advocate that the advanced communication technologies required for telepharmacy telehealth be available in to rural and or medically underserved populations areas; further,

To advocate for funding of loan forgiveness or incentive programs that recruit pharmacists and pharmacy technicians to practice in rural and or medically underserved populations areas.

*3. Interstate Pharmacist Licensure

To advocate for multistate interstate pharmacist licensure to expand the mobility of pharmacists and their ability to practice remotely.

*4. Continuity of Care in Insurance Payer Networks

To oppose provider access criteria that impose <u>discriminatory</u> requirements or qualifications on participation in pharmacy insurance payer networks that interfere with patient continuity of care or patient site-of-care options.

5. Health-System Use of Medications Supplied to Hospitals by Patients, Caregivers, or Specialty Pharmacies

[CLAUSE MOVED]To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

To encourage hospitals and health systems not to permit administration of medications brought supplied to the hospital or clinic by the patient, caregiver, or specialty pharmacy when storage conditions or the source cannot be verified, unless it is determined that the risk of not using such a medication exceeds the risk of using it; further,

[CLAUSE MOVED]To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further:

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications.

Note: This policy would supersede ASHP policy 0806.

6. Health-System Use of Administration Devices Supplied Directly to Patients

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients), unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To encourage hospitals and health systems to train staff on the handling and use of medication administration devices brought in by patients; further,

To recommend that hospitals and health systems have a system in place for determining the risk versus benefit of permitting a patient to use his or her own medication administration devices; further,

To advocate that hospitals and health systems have policies and procedures, including the training of staff, on the use and management of medication administration devices and devices that augment medication administration (e.g., continuous glucose monitors); further,

[CLAUSE MOVED]To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team; further,

To advocate for adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices; further,

[CLAUSE MOVED] To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team.

Note: This policy would supersede ASHP policy 0806.

7. Staffing for Safe and Effective Patient Care

To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care and employee engagement; further,

To encourage pharmacy leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, <u>telehealth</u> practices, legal requirements, accreditation

standards, professional standards of practice, and the resources and technology available in individual settings; further,

To support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care;
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services; and
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24 hour access to a pharmacist.

Note: This policy would supersede ASHP policy 0201.

The policy recommendation from the **Council on Pharmacy Practice** was presented.

1. Role of the Pharmacy Workforce in Violence Prevention

To recognize that violence in the U.S. is a public health crisis; further,

To affirm that the pharmacy workforce has important roles in a comprehensive public health and medical approach to violence prevention, including leadership roles in their communities and workplaces; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in violence prevention efforts in their communities and workplaces; further,

To promote collaboration between the pharmacy workforce and community and healthcare organizations in violence prevention efforts; further,

To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in violence prevention; further,

To support research and dissemination of information on the effectiveness of pharmacy-focused violence-prevention strategies.

New Business. Chair White announced that, in accordance with Article 7 of the Bylaws, there were two items of New Business to be considered. Chair White called on Mollie Scott (North Carolina) to introduce the item of New Business, "Racial and Discriminatory Inequities" (Appendix IV.a). Following discussion, the item was approved for action by ASHP. It reads as follows:

Racial and Discriminatory Inequities

Motion:

- 1. To acknowledge that racism, discrimination, and inequities exist in healthcare and society as a whole; further,
- 2. To assert that racism, or any form of discrimination or injustice, has no positive

value in society and cannot be tolerated; further,

3. To feverently commit to creating a more just and inclusive healthcare system and society as a whole.

SUGGESTED OUTCOMES:

- 1. Form a diverse, representative task force and convene a summit to study systemic racism with the goal of creating new resources and deliverables form embers that contribute to breaking down the barriers that contribute to systemic racism in healthcare and society as a whole.
- 2. Prioritize the development of workshops and symposia for national meetings (i.e., ASHP Clinical Midyear, ASHP Summer Meeting, ASHP Preceptors Conference, ASHP Leadership Conference, and student conferences) that educate members on implicit bias and systemic racism that seek to dismantle racism, prejudice and ethnic oppression, and support freedom and human dignity.
- 3. Perform a comprehensive review of existing ASHP policies (i.e., Cultural Competence, Racial and Ethnic Disparities in Healthcare) to ensure that they are up-to-date and reflect ASHP's commitment to standing against racism of any kind.
- 4. Establish a Section Advisory Group on Inclusion, Diversity, and Racial Equity within the new Section of Pharmacy Educators to develop recommendations and best practices in pharmacy education that positively impact the next generation of pharmacists and technicians.
- 5. Request that each ASHP Section and Forum identify a plan for addressing racial, discriminatory inequities in healthcare within their charges and deliverables.
- 6. Incorporate new standards for education about implicit bias and systemic racism into ASHP-accredited programs including residency programs and technician programs.

- 7. Engage the pharmacy workforce in listening meetings that seek to understand the impact of racism on the lives of African American patients and healthcare professionals and identify strategies to improve healthcare equity and create an inclusive pharmacy workforce.
- 8. Create an ASHP Connect community that promotes health equity and social justice and showcases blogs and stories of how systemic racism impacts patients and healthcare professionals as well as success stories from individuals and organizations who are striving to promote human dignity and dismantle racism.
- 9. Establish new collaborations with organizations both inside and outside of pharmacy who have demonstrated commitment to decreasing health inequities (e.g., American Medical Association, American Public Health Association, HBCUs, and NAACP).
- 10. Create and implement an action plan for recruitment of under-represented minorities to the profession of pharmacy in order to ensure that the pharmacy workforce reflects our patient populations.

Chair White called on Marianne Ivey (Past President) to introduce the next item of New Business, "ASHP Support of the World Health Organization" (Appendix IV.b). Following discussion, the item was approved for action by ASHP. It reads as follows:

ASHP Support of the World Health Organization

Motion:

1. To encourage ASHP and its members to strongly support the mission work of the World Health Organization (WHO) in its role in public health preparedness, prevention, and control to improve the health and wellbeing of people globally; further,

2. To prioritize the revision of the ASHP Statement on the Role of Health-System Pharmacists in Public Health.

Background

In an age of global travel between and among countries the efforts to prevent, control, treat and eradicate diseases and conditions that decrease health and well-being of all peoples are critical to all countries independent of factors such as income and education. Addressing new vectors of disease transmission and behavioral conditions related to lifestyles and environmental conditions continue to provide challenges that need to be addressed. Agencies such as WHO that provide evidence-based warnings, guidelines, education, research and advocacy and collect data to help countries prepare their public health infrastructure are critical in providing all peoples with the tools and resources needed to address critical health issues globally. The current ASHP Statement on the Role of Health-System Pharmacists in Public Health was published in 2008 and should be reviewed and updated.

SUGGESTED OUTCOMES:

The ASHP HOD will approve this new business and emphasize the importance of the role of WHO through its statement on the role of pharmacists in public health.

Report of the Chair of the Board and the Chief Executive Officer. The Chair directed the delegates' attention to the report, which was posted online. There was no discussion, and the delegates voted to accept the Report of the Chair of the Board and the Chief Executive Officer (Appendix V).

Report of the Treasurer. The Chair directed the delegates' attention to the Report of the Treasurer (Appendix VI), which was posted online. There was no discussion.

The meeting adjourned at 3:00 p.m.

Second meeting

The second and final meeting of the House of Delegates session convened on Tuesday, June 9, at 2:00 p.m. A quorum was present.

Board of Directors duly considered matters. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 8 to "duly consider" the policies amended at the first meeting. Four policy recommendations were approved without amendment. Thirteen policy recommendations were amended by the House of Delegates, with suggested nonsubstantive editorial changes to four policy recommendations. The Board agreed with all the House's amendments and editorial changes, with minor editorial changes to two of the amended policies to increase their clarity or provide consistency with other ASHP policies. The Board also duly considered and approved the two items of New Business.

Recommendations. Chair White called on members of the House of Delegates for Recommendations. (See Appendix VII for a complete listing of all Recommendations.)

Recognition. Chair White recognized members of the Board who were continuing in office (Appendix VIII). He also introduced members of the Board who were completing their terms of office.

As a token of appreciation on behalf of the Board of Directors and members of ASHP, Chair White noted that Immediate Past President Pawlicki will receive by mail an inscribed gavel commemorating her term of office.

Installation. Chair White then installed Thomas J. Johnson as President of ASHP, Leigh A. Briscoe-Dwyer and Jamie Sinclair as members of the Board of Directors (Appendix VIII). (See Appendix IX for the Inaugural Address of the Incoming President.)

Adjournment. The 72nd annual June meeting of the House of Delegates adjourned at 3:00 p.m.

^aThe Committee on Nominations consisted of Meghan Swarthout, Chair (MD); Lisa Gersema, Vice Chair (MN); Noelle Chapman (IL); James Hoffman (TN); Molly Leber (CT); Steven Riddle (WA); and Kethen So (CA).

HOUSE OF DELEGATES ATTENDANCE ROSTER (JUNE 2020)

Casey H. White, Chair Kelly M. Smith, Vice Chair

As of June 16, 2020

As of June 16, 2020 OFFICERS AND BOARD OF D	IDECTORS		
Kathleen S. Pawlicki, President			
Thomas Johnson, President			
Kelly M. Smith, Immediate F			
Casey H. White, Chair, Hous	-		
Christene M. Jolowsky, Trea			
Paul W. Abramowitz, Chief E			
Leigh Briscoe-Dwyer, Board			
·	ison, Council on Pharmacy Manage		
•	ison, Commission on Affiliate Relat	tions	
Julie A. Groppi, Board Liaiso	•		
•	Liaison, Council on Therapeutics		
Jamie Sinclair, Board Memb			
•	n, Council on Pharmacy Practice		
·	on, Council on Education and Worl	force Development	
PAST PRESIDENTS			
R. David Anderson	Diane Ginsburg	Sara White	
Roger Anderson	Harold Godwin	David Zilz	
John Armitstead	Clifford Hynniman		
Daniel Ashby	Marianne Ivey		
R. Paul Baumgartner	Stan Kent		
Jannet Carmichael	Robert Lantos		
Debra Devereaux	Jill Martin Boone		
Fred Eckel	Philip Schneider		
Rebecca Finley	Kathryn Schultz		
Lisa Gersema	Steven Sheaffer		
STATE	DELEGATES	ALTERNATES	
Alabama (3)	Whitney White	Charles Cook	
	Thomas Achey		
	Lea Eiland		
Alaska (2)	Ursula Iha	Michelle Locke	
	Gretchen Glaspy	Nancy Frei	
Arizona (3)	Melinda Burnworth	Carol Rollins	
	Christi Jen		ļ
	Christopher Edwards		
Arkansas (2)	Rayanne Story		
	Christy Agee		ļ
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			ļ
			ļ

California (7)	Lisa Gunther Lum	Sarah McBane ^{1,2}
Camornia (7)	Keith Yoshizuka	Daniel Kudo
	Steven Thompson	Burner Rado
	Kethen So	
	Brian Kawahara	
	Donald Kishi	
Colorado (3)	Michelle Then	Sarah Anderson
Colorado (3)	Jennifer Davis ²	Sarah Anderson
	Karen McConnell	
Connecticut (3)	Molly Billstein Leber	Lorraine Lee
connecticat (3)	LeeAnn Miller ²	Lorraine Lee
	David Goffman ²	
	David Gorillan	
Delaware (2)	Cheri Briggs	Samantha Landolfa
20.0	Sumit Gandotra	23.73.73.73
Florida (5)	William Kernan ¹	Farima Fakheri Raof ²
	Jeff Bush	
	Gary Dalin	
	Dave Lacknauth	
	Michael DeCoske	
Georgia (3)	Trisha Branan	Brittany Wheeler
5 ()	Collin Lee	,
	Susan Jackson	
Hawaii (2)	Joy Matsuyama	
()	Hope Kimura	
Idaho (2)	Arielle Arnold	Paul Driver
	Heather Walser	
Illinois (5)	Christopher Crank	Alifiya Hyderi
	Jennifer Phillips	Carrie Sincak
	Andy Donnelly	Scott Meyers
	Bernice Man	Trish Wegner
	Charlene Hope ²	
Indiana (3)	Christopher Scott	John Hertig
	Chris Lowe	
	Tate Trujillo	
Iowa (3)	John Hamiel	Anthony Pudlo
	Diane Reist	
	Terrel Wiedenfeld	
Kansas (3)	Jeffrey Little	Joanna Robinson
	Jennifer McKenna	Katie Wilson
	Katherine Miller	
Kentucky (3)	Scott Hayes	Dale English
	Devlin Smith	Robert Lewis
	Joan Haltom	Leslie Kenney
Louisiana (3)	Monica Dziuba	Jason Chou
	Joseph Gary LeBlanc	Katie Aymond
	Christopher Gillard	

¹ denotes attendance on Sunday, June 7 ² denotes attendance on Tuesday, June 9

Maine (2)	Matthew Christie	
	Kathryn Sawicki	
Maryland (4)	Kristin Watson	Janet Lee
(. ,	Joshua Blackwell	Nicole Kiehle
	Tara Feller	
	Molly Wascher	
Massachusetts (4)	Erin Taylor	Ben Pennell
(1)	Caryn Belisle	
	Jackie MacCormack-Gagnon	
	Monica Mahoney	
Michigan (4)	Ryan Bickel	James Lile
3 ()	, Michael Ruffing	Dianne Malburg
	Jesse Hogue	S S
	Margaret Malovrh	
Minnesota (3)	Tamara Bezdicek	Rachel Root
	Kevin Dillon	Brandon Ordway
	Paul Krogh	Jessica Swearingen
Mississippi (3)	Josh Fleming	Todd Dear
	Andrew Mays	
	Anees Kanorwala	
Missouri (3)	Laura Butkievich	Davina Dell Steinbeck
	Emily Owen	Amy Sipe
	Joel Hennenfent	Alexandra Oschman
		Mohamed Adbulwahhab
Montana (2)	Jason Nickisch	Starla Blank
	Hugh Easley	
Nebraska (3)	Ken Kester	Michele Faulkner
	Katie Reisbig	Kim Lueders
	Jerome Wohleb	
Nevada (2)	Kate Ward	
	Adam Porath	
New Hampshire (2)	Kristine Willett	Dave DePiero
	Keith Foster	
New Jersey (4)	William Herlihy	Barbara Giacomelli
	Jessica Hill	Deborah Sadowski
	Julie Kalabalik	Malgorzata Slugocki
	Nissy Varughese	
New Mexico (2)	Melanie Dodd	Charles "Kurt" Mahan
	Traci White	
New York (5)	Heide Christensen	Angela Cheng
	Ruth Cassidy	Travis Dick
	Frank Sosnowski	Mohammad Islam
	Elizabeth Shlom	
	Karen Berger	

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North Carolina (4)	Susan Bear	Tylor Voct
North Carolina (4)	Michael Melroy	Tyler Vest
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	Mary Parker	
	Mollie Scott	
North Dakota (2)	Brody Maack ²	
	Maari Loy	
Ohio (5)	Rachel Chandra	Michael Hoying
	Amanda Hansen	Robert Parsons
	Harrison Jozefczyk	Russell Smith
	Karen Kier	Rebecca Taylor
	Jason Milner	Mary Temple-Cooper
Oklahoma (3)	Lisa Mayer	Christopher Pack
	Brian Hughes	
	Edna Patatanian	
Oregon (3)	Andrew Gibler	Zach McCall
	Victoria Wallace	
	Katie Norton	
Pennsylvania (4)	Jean Scholtz	Lawrence Carey ¹
	Christine Roussel	Chantel Farrello
	Dave Zimmerman	Lawrence Jones
	Brad Cooper ²	
Puerto Rico (2)	·	
Rhode Island (2)	Mark Rogers	Martha Roberts
	Shannon Levesque	Karen Nolan
South Carolina (3)	Lynn Ethridge	Bradley White
	Heather Easterling	Natasha Nicol
South Dakota (2)	Andrea Darr	Jaclynn Chin
	Tadd Hellwig	Laura Stoebner
Tennessee (4)	Don Branam	Lakesha Farmer
	Justin Griner ¹	Nikki Sowards
	Jennifer Robertson	Sarah Hardeman
	Joseph Krushinski	Micah Cost ²
Texas (6)	Tammy Cohen	Binita Patel
	Steven Knight	
	Tricia Meyer	
	Sarah Lake-Wallace	
	Randy Martin	
	Kirk Evoy	
Utah (3)	Erin Fox	Michelle Wheeler
	Anthony Trovato	Tina Aramaki
	Kavish Choudhary	Wilson Pace
Vermont (2)	Jeffrey Schnoor	Wes McMillian
Cimone (2)	Kevin Marvin ²	vvc3 iviciviiiiaii
	ICVIII IVIAI VIII	

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Virginia (4)	Lisa Hammond	Kathy Koehl
	Katelyn Hipwell ²	
	Craig Kirkwood	
	Natalie Nguyen	
Washington, D.C. (2)	Kong Wong	Meenakshi Shelat
	Michelle Eby	
Washington State (4)	Roger Woolf	Megan Willson
	Cyndy Clegg	Rena Gosser
	Karen White	
	Susan Boyer	
West Virginia (2)	Doug Slain	
Wisconsin (4)	Christina Andros	Tom Dilworth
	Terry Audley	Kate Schaafsma
	David Hager	John Muchka
(2)	Justin Konkol	Lucas Schulz
Wyoming (2)	Jamie Homecker	
CECTIONIC AND EQUINAC	Tonja Woods	ALTERNIATES
SECTIONS AND FORUMS	DELEGATES Zeach and Machan	ALTERNATES
Ambulatory Care Practitioners	Zachary Weber	Jessica Skelley
Clinical Specialists and Scientists	Aaron Steffenhagen	Joel Marrs
Inpatient Care Practitioners	Douglas Meyer	Gregory Burger
Pharmacy Informatics and	Samm Anderegg	Seth Hartman
Technology		
Pharmacy Practice Leaders	Samuel Calabrese	Philip Brummond
Specialty Pharmacy	JoAnn Stubbings	Matthew Rim
Practitioners		
New Practitioners Forum	Kellie Musch	Erin Boswell
Pharmacy Student Forum	Jeffrey Clark	Autumn Pinard
Pharmacy Technician Forum	Glen Gard	JoAnne Myhre
FRATERNAL	DELEGATES	ALTERNATES
U.S. Air Force	Maj. Jin Kim	Maj. Miranda Debelevich
U.S. Army	LTC Rob Brutcher	LTC Joe Taylor
U.S. Navy		LT Chirag Patel
U.S. Public Health Service		CDR Carl Coates
Veterans Affairs	Dr. Heather Ourth	Dr. Virginia Torrise

¹ denotes attendance on Sunday, June 7 ² denotes attendance on Tuesday, June 9



House of Delegates

HOUSE OF DELEGATES

REPORT OF THE

COMMITTEE ON NOMINATIONS

June 7, 2020

Online Meeting

Meghan Swarthout (Chair), Maryland
Lisa Gersema (Vice Chair), Minnesota
Noelle Chapman, Illinois
James Hoffman, Tennessee
Molly Leber, Connecticut
Steven Riddle, Washington
Kethen So, California
Christopher Fortier (1st Alternate), Massachusetts
Kristine Gullickson (2nd Alternate), Minnesota
Lisa Mascardo (3rd Alternate), Iowa

ASHP COMMITTEE ON NOMINATIONS

Mister Chair, Fellow Delegates:

The Committee on Nominations consists of seven members of ASHP who were members of the House of Delegates at the time of their appointment. The Committee is appointed by the Chair of the House of Delegates and is charged with the task of presenting to you our best judgments about those persons who possess the tangible and intangible attributes of leadership that qualify them to serve as our officers and directors.

Selection of nominees for ASHP office involves a series of very challenging decisions on the part of the Committee. Ultimately, those decisions are intended to permit the membership to select leaders with the professional, intellectual, and personal qualities of leadership that will sustain the dynamism and pioneering spirit that have characterized both ASHP and its more than 50,000 members who provide patient care service across the entire spectrum of care.

First, the Committee must determine that a prospective nominee for office is an active member as required in the Charter. This is generally the easiest and most straightforward part of the Committee's work. The Committee must ascertain that each prospective nominee can perform the duties required of the office or offices to which he or she has been nominated. All nominees must be able to perform the duties of a Director, set forth in section 5.4 of the Bylaws. Presidential nominees must also be able to perform the duties of that office, set forth in article 4 of the Bylaws.

The more difficult part of the Committee's work is to assess those intangible qualities of emotional intelligence (empathy, self-awareness, self-regulation, social skills, and motivation), leadership, vision, engagement, and overall professional awareness that characterize the standout candidates – those truly able to provide leadership for ASHP and the profession. The Committee assesses the attributes of prospective candidates for office in areas such as:

- Professional experience, career path, and practice orientation.
- Leadership skills and leadership experience including but not limited to the extent of leadership involvement in ASHP and its affiliates.
- Knowledge of pharmacy practice and vision for practice and ASHP.
- Ability to represent ASHP's diverse membership interests and perspectives.
- Communication and consensus building skills.

There are no right or wrong answers to these criteria. Certain qualities may be weighed differently at various points in the evolution of the profession.

The Committee's year-long process of receiving nominations and screening candidates is designed to solicit extensive membership input and, ultimately, to permit the Committee to candidly and confidentially assess which candidates best fit ASHP's needs. The Committee has met twice in person since the last session of the House of Delegates: on December 10, 2019, at the Midyear Clinical Meeting in Las Vegas, Nevada; and on April 22, 2020, via teleconference. Review of nominees' materials was conducted continuously between March and April 2020 solely via secure electronic transmissions. This process has been reviewed for quality improvement and will be repeated for the 2020–2021 nomination cycle.

As in the past, the Committee used various means to canvass ASHP members and state affiliates for candidates who they felt were most qualified to lead us. All members were invited via announcements in ASHP News and Daily Briefing, social media, online ASHP NewsLink bulletins, and the ASHP website to submit nominations for the Committee's consideration. Nominations from affiliated state societies were solicited through special mailings and the "state affiliate" edition of the online NewsLink service. At the 2019 Midyear Clinical Meeting, the Chair and ASHP Chief Executive Officer made themselves available to receive nominations personally in a location and at a time that were publicized in ASHP news publications and correspondence.

Based upon recommendations from membership, state affiliates, and ASHP staff, the Committee contacted over 678 individuals identified as possible candidates. Some individuals were invited to accept consideration for more than one office. Of the nominees who responded to the invitation to place themselves in nomination, the breakdown by office is as follows:

PRESIDENT-ELECT: 5 accepted BOARD OF DIRECTORS: 10 accepted

A list of candidates that were slated was provided to delegates following the Committee's meeting on April 22, 2020.

The Committee is pleased to place in official nomination the following candidates for election to the indicated offices. Names, biographical data, and statements have been distributed to the House.

President-Elect

Lea S. Eiland, Pharm.D., BCPPS, BCPS, FASHP, FPPA (Auburn, AL) Linda S. Tyler, Pharm.D., FASHP (Salt Lake City, UT)

Board of Directors

Kim W. Benner, Pharm.D., BCPS, FASHP, FPPA (Homewood, AL)
Dan Degnan, Pharm.D., M.S., CPPS, FASHP (West Lafayette, IN)
Neil J. MacKinnon, B.S.Pharm., Ph.D., M.S., FCSHP, FNAP (Cincinnati, OH)
Pamela K. Phelps, Pharm.D., FASHP, FMSHP (Minneapolis, MN)

Mister Chair, this completes the presentation of candidates by the Committee on Nominations. Congratulations to all the candidates.

CANDIDATES FOR PRESIDENT 2021–2022

Lea S. Eiland, Pharm.D., BCPPS, BCPS, FASHP, FPPA (eilanls@auburn.edu) is a Clinical Professor and Associate Department Head of Pharmacy Practice, Auburn University Harrison School of Pharmacy, and Clinical Professor of Pediatrics, University of Alabama at Birmingham School of Medicine. She earned her Pharm.D. from The University of Texas at Austin and completed an ASHP-accredited pediatric specialty residency at Texas Tech University. Eiland has championed implementing medication safety initiatives and dose optimization strategies to improve patient outcomes while developing services in the pediatric ICU, general pediatric inpatient, and pediatric ambulatory care settings. Her career has focused on clinical practice, interprofessional education, research/scholarship, and leadership.

Eiland's service to ASHP has spanned her entire career, including the Board of Directors; Director-at-Large and Chair of the Section of Clinical Specialists and Scientists Executive Committee; Member, Vice-Chair, and Chair of the Council on Education and Workforce Development; House of Delegates; Women in Pharmacy Leadership Steering Committee; EVP/CEO Search and Screen Committee; Task Force on Pharmacy's Changing Demographics; and Task Force on Organizational Structure. She is the lead author of 2018 ASHP–PPAG Guidelines for Providing Pediatric Pharmacy Services in Hospitals and Health Systems. Eiland is a SSHP faculty advisor at Auburn, a Past President of ALSHP, and received the 2008 ALSHP Pharmacist of the Year Award.

Statement:

During times of adversity, we learn of our resilience and agility in managing challenges. The members and staff of ASHP have responded in many ways during these last several months of national and global crisis. By actively connecting members with resources, services, and expertise, and by tirelessly advocating for our patients, we have continued to demonstrate the value and purpose of professional organizations, and ASHP has led the way. Moving forward, our organization must remain adaptable by anticipating and evaluating changes in patient care, the profession, and our members' needs while focusing on opportunities that support the core ASHP values and purpose.

As we support our patients and members during this healthcare transformation, ASHP must:

- Embrace the changing delivery of healthcare and innovative ways pharmacists and technicians care for patients.
- Advocate for our patients and profession.
- Continue to seek strong collaboration with other organizations regarding healthcare initiatives to benefit our patients, members, and profession.
- Remain the paramount pharmacy organization others seek for guidance and partnership in pharmacy-related opportunities or concerns.

I would be honored and excited to serve as your President, leading ASHP in shaping the future of pharmacy. I thank each of you for your contributions to ASHP, our profession, and working together as pharmacists advancing healthcare.

Linda S. Tyler, Pharm.D., FASHP (linda.tyler@hsc.utah.edu), is the Chief Pharmacy Officer for University of Utah Health; Professor (Clinical), Department of Pharmacotherapy and Associate Dean for Pharmacy Practice, University of Utah College of Pharmacy. Tyler received her B.S. in Pharmacy and Pharm.D. degrees from the University of Utah. She completed a pharmacy practice residency at University of Nebraska Medical Center. She was a faculty member and critical care practitioner at the

University of Wisconsin and a poison control center specialist at Nationwide Children's Hospital. She returned to the University of Utah as Director of Drug Information Services. She served in that role for many years before becoming the senior pharmacy leader for University of Utah Health. She is the residency program director for the HSPAL program. Tyler is a tireless advocate for progressive and innovative pharmacy services in health systems.

Tyler has served ASHP in many capacities, most recently as a Board Member. She previously served as Chair of the Council on Pharmacy Management and as Director-at-Large of the Section of Clinical Specialists and Scientists Executive Committee. She has also served on the Councils on Organizational Affairs, Therapeutics, Education and Workforce Development, and Pharmacy Practice; the Committee on Nominations; Section of Ambulatory Care Practitioners; New Practitioner and Student Forums; and a delegate to the House of Delegates for several years. She is a Past President of USHP. Dr. Tyler was the 2015 recipient of the John Webb Award, given by ASHP in recognition of outstanding leadership.

Statement:

I joined ASHP thinking that ASHP would advocate for me. Somewhere along the way, I realized that ASHP was its members, members like me. ASHP serves as a multiplier for each of us, amplifying our voices to make a difference. We need to speak out and act in three pivotal areas.

- Empower our workforce by optimizing our capabilities, achieving the right skill mix, and addressing the issues of resiliency and burnout.
- Create value for our patients, health systems, and communities. We are in a pivotal role to manage healthcare expenses and improve quality.
- Lead on critical medication issues such as improving the integrity of the medication supply chain; preventing drug shortages; addressing the opioid crisis; reducing medication-related events; building safer healthcare systems; and helping patients obtain access to critical medications they need.

We are living in unprecedented times. None of us could have predicted the changes we have experienced in the last few months. This will forever change how we do our work. Now is the time to accelerate change. We have unlimited opportunity to demonstrate we are the critical ingredient in healthcare teams to achieve optimal medication outcomes as we care for patients across the continuum of care.

Now is the time—ASHP, you, can shape the new future of our profession.

I am humbled to be nominated and would be honored to serve as President of ASHP.

CANDIDATES FOR BOARD OF DIRECTORS 2021–2024

Kim W. Benner, Pharm.D., BCPS, FASHP, FPPA (kwbenner@samford.edu) is Professor of Pharmacy Practice at Samford University McWhorter School of Pharmacy and Pediatric Specialist at Children's of Alabama. After earning her Doctor of Pharmacy degree at Samford, Benner completed an ASHP-accredited residency at Children's of Alabama. Areas of specialty include pediatrics (specific experience in critical care and pulmonary), dermatology, translational research, and simulation education. Teaching is directed towards students, residents, fellow pharmacists, and other healthcare professionals both at Samford University and Children's Hospital; other teaching-related duties include coordination of a teaching and learning certificate program for local pharmacy residents. Benner serves as the faculty advisor for the Samford SSHP chapter, the same one she chartered over 20 years ago.

ASHP related activities include Past Chair of the Section of Clinical Specialists and Scientists, Committee on Nominations, and Council on Therapeutics. Benner has also served as an ASHP Clinical Skills Competition (CSC) coordinator and judge, Alabama delegate (6 years), CV and meeting proposal/abstract reviewer, and on various Section/ad hoc committees. Current ASHP activities include: CSC judge and member of the Section of Clinical Specialists and Scientists SAG on Pediatrics and Committee on Nominations. Alabama ASHP state affiliate work includes past Council Director and President and (current) Student Activities Committee Chair. Benner was appointed and served three years on the inaugural Board of Pharmacy Specialties Pediatric Council.

Statement:

"It's a beautiful thing when a career and passion come together." – unknown

My pharmacy career path is paved with much passion and energy; ASHP became part of my journey as a pharmacy student chartering a new chapter. Since then, I have learned the value of membership, understand the people we serve, and witnessed the voice of advocacy. ASHP has always been at the forefront of our profession and thus was chosen as my professional home to share that passion and energy. I have been blessed with a career that allows me to engage in patient care while ensuring the future of our profession through education. When mentoring others, I share my passion for ASHP and the impact such a professional organization can have on our profession.

ASHP is uniquely poised to continue positively impacting health-system pharmacy. In my experience with ASHP, emerging priorities include:

- Meeting educational demands of varying member types and practice areas.
- Addressing needs of practitioners for advanced practice agreements, provider status, and credentialing.
- Engaging students and residents to ensure the future of ASHP membership.
- Providing a unique experience that benefits and engages its members while also continuing to collaborate with other organizations.
- Continuing wellness endeavors to ensure a thriving pharmacy workforce.

If elected, I will share my passion and energy to help move ASHP forward. Over the years I have befriended many within ASHP and would love the opportunity to meet more of you and represent you all on the ASHP Board of Directors!

Dan Degnan, Pharm.D., M.S., CPPS, FASHP (ddegnan@purdue.edu) currently serves as Associate Director for the Professional Program Laboratory and is a Clinical Assistant Professor of Pharmacy

Practice (Courtesy) at Purdue University College of Pharmacy. Degnan has an appointment with Regenstrief Center for Healthcare Engineering at Purdue as a Clinical Research Associate with research interests in the areas of pharmacy automation and high-reliability healthcare. Before coming to Purdue, Degnan served as the Medication Safety Officer at Community Health Network in Indianapolis.

Degnan earned his Pharm.D. from Purdue University. He completed a specialty residency in pharmacy administration and an M.S. in Pharmacy Administration at the University of Wisconsin.

Degnan's service to ASHP includes Chair, Council on Organizational Affairs; Chair, Committee on Nominations; Chair, Section of Inpatient Care Practitioners; and state delegate to ASHP from Indiana for many years. Degnan has served in many state affiliate roles, including President of the Indiana Society.

Statement:

Embracing the issues that face our profession and curating effective and meaningful ways to improve them should be the work of all of us, including ASHP. Moving forward, ASHP should enhance its efforts to move the profession forward in the following areas:

- Aligning supply chain management incentives with the needs of patients and healthcare organizations.
- Promoting a rich environment for innovation and growth in postgraduate residency programs.
- Focusing on development of robust clinical well-being, resilience, and burnout mitigation resources, including profession-specific research on the issue.
- Developing the concepts of professionalism, ethics, and caring in pharmacy so that the narrative and context around a patient's care are viewed as critical to the provision of care.

My personal and professional philosophy includes a longstanding commitment to the principles of servant leadership, lifelong learning, and demonstrating an empathetic approach to helping others. These principles have been applied throughout my career and lend themselves to the concept of a constant pursuit of excellence. ASHP and our profession deserve no less.

It is an honor to be on the slate of candidates for the ASHP Board of Directors. I would truly appreciate the opportunity to serve on the ASHP Board of Directors.

Neil J. MacKinnon, B.S.Pharm., Ph.D., M.S., FCSHP, FNAP (RxDeanMac@uc.edu) is Dean and Professor at the University of Cincinnati. Previously, he was Director of the State Office of Rural Health for the State of Arizona and Professor at the Mel and Enid Zuckerman College of Public Health, University of Arizona. He obtained his pharmacy degree from Dalhousie University in Canada, completed the M.S./administrative hospital pharmacy residency program at the University of Wisconsin Hospital and Clinics, and a Ph.D. and fellowship at the University of Florida. He is passionate about the critical role of pharmacists in public health and how health-system pharmacists can contribute to a safe and effective medication-use system.

MacKinnon's ASHP service includes the Commission on Goals, Council on Education and Workforce Development, Council on Pharmacy Management, Dean's Advisory Panel, the Section of Pharmacy Practice Managers Advisory Group (SAG) on Leadership Development, Section of Inpatient Care Practitioners SAGs on Pharmacy Practice Experiences and Small and Rural Hospitals. He is a Past President of the Canadian Society of Hospital Pharmacists and the 2017 recipient of the ASHP/Association of Black Health-System Pharmacists (ABHP) Leadership Award.

Statement:

Health-system pharmacy is stronger with a robust and vibrant ASHP. My interest in serving on the Board of Directors stems from my desire to help ASHP, which, in turn, will help our profession. Looking forward, I believe there are three key issues/opportunities for ASHP in the coming months and years.

First, COVID-19 has demonstrated the critical importance of public health and how it can impact all facets of our lives. As a former faculty member at a college of public health, I see much opportunity for our profession in public health. There is much that ASHP could do to ensure that health-system pharmacists are widely recognized as an integral part of all public health strategies and policies moving forward.

Second, for any professional organization, the key to success is the value proposition for its members (and prospective members). Why would someone join ASHP, and what value do they receive from that membership? This is especially critical during challenging economic times when the salaries of many health-system pharmacists and technicians have been reduced and travel is restricted.

The third critical issue facing ASHP is risk management. This includes assessing all risks and threats and developing contingency plans. This type of activity may be invisible to most members of ASHP but must be a focus of the Board. For example, given the ripple effects of COVID-19, what are the main threats to ASHP's health, and how is the organization preparing to deal with those threats?

Pamela K. Phelps, Pharm.D., FASHP, FMSHP (pphelps2@fairview.org), is System Director of Acute Care Clinical Pharmacy Services at M Health Fairview, an 11-hospital health system in Minneapolis, MN. She is Clinical Associate Professor at the University of Minnesota College of Pharmacy. A Minnesota alum, she began her career as a staff pharmacist, followed by pharmacy specialist in critical care, before moving into formal leadership roles. She is Chief Executive for M Health Fairview's residency programs and PGY1 Residency Program Director at the University of Minnesota Medical Center, graduating 161 residents during her tenure. Dr. Phelps has 35 peer-reviewed articles and has given 61 invited presentations.

Dr. Phelps' service to ASHP includes Chair of the Council on Therapeutics, ASHP Advisory Committee for the Pharmacy Forecast, chapter author for the Pharmacy Forecast, editor for the ASHP book, *Smart Infusion Pumps*, member of the ASHP Task Force on Accountable Care Organizations, Minnesota State Delegate, and ASHP Council on Educational Affairs. She has served as a Chair and Executive Board Member for the Vizient Pharmacy Council. Phelps has served in many state affiliation roles, including President and Board Member of the Minnesota Society. She has served as Public Policy Co-Chair for MSHP for the past three years.

Statement:

Never have pharmacists been more essential to the health of our communities. We don't know what models of care will be in effect after the COVID pandemic, but we do know that we are likely to continue with models that care for patients to keep them "safe at home." It is imperative for our pharmacy leadership to seize this opportunity to advance the profession for the sake of our patients. Expansion of our scope of practice, telehealth, remote consultations, and expansion of compounding services have become a part of our new reality. This new reality is a real opportunity to build frameworks for care, consultation, and the recognition we have been seeking. Provider status is critical for pharmacists providing care under these conditions. At the same time, we find our education and training programs stressed under social distancing challenges. We need to support these systems with new models and programs to ensure the vitality of the profession. The professional stress in these times can be daunting. Finally, technician training and advancement programs are needed to keep the heartbeat of the pharmacy beating.

Yes, we face unprecedented challenges. Let's use these challenges as a means to create bold strategies that drive the profession forward, support our membership health and well-being, bolster support for technician development and retention, address enormous financial challenges, and ensure public access to a pharmacist's care.

I have never been prouder of our profession, and would be truly honored to represent the membership on the Board of Directors.



House of Delegates

Board of Directors Report: Policy Recommendations for the June 2020 House of Delegates

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Contents: Policy Recommendations for the June 2020 ASHP House of Delegates

COUNCIL ON PUBLIC POLICY POLICY RECOMMENDATIONS

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice. Within the Council's purview are (1) federal laws and regulations, (2) state laws and regulations, (3) analysis of public policy proposals that are designed to address important health issues, (4) professional liability as defined by the courts, and (5) related matters.

Julie A. Groppi, *Board Liaison*

Council Members

Jeff Little, Chair (Kansas)
Steve Riddle, Vice Chair (Washington)
Roy Guharoy (Alabama)
Charzetta James (Florida)
Rusol Karralli (Texas)
Janet Lee (Maryland)
Luke Miller (Texas)
Adam Porath (Nevada)
Elizabeth Rodman, New Practitioner
(Wisconsin)
Jeffrey Schnoor (Vermont)
Elizabeth Shlom (New York)
Jennifer Wang Tomlinson, Student (Colorado)

Jillanne Schulte Wall, Secretary

1. Access to Affordable Healthcare

- To advocate for access to affordable healthcare for all residents of the United States,
- including coverage of medications and related pharmacist patient care services; further,
- To advocate that the full range of available methods be used to (1) ensure the provision
- of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment
- outcomes; (3) minimize overall costs without compromising quality; and (4) ensure
- 6 patient choice of healthcare providers, including pharmacy services; further,
- 7 To advocate that healthcare payers seek to optimize continuity of care in their design of
- 8 benefit plans.

Note: This policy would supersede ASHP policy 1001.

Rationale

This policy expresses ASHP's stance on access to healthcare in the United States. The policy emanated from ASHP policies dealing with affordability and accessibility of pharmaceuticals. ASHP believes that it is important to address the larger issue of healthcare access, particularly due to the impact of the cost of medications on the nation's overall healthcare budget as well



as pharmacy budgets in hospitals and health systems. Healthcare should be affordable, but also sufficient to ensure patient access to services.

Background

The Council reviewed ASHP policy 1001, Health Insurance Coverage for U.S. Residents, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; <u>strikethrough</u> indicates deletions):

To advocate for health insurance access to affordable healthcare for all residents of the United States, including coverage of medications and related pharmacist patient care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment outcomes; and (3) minimize overall costs without compromising quality; and (4) ensure patient choice of healthcare providers, including pharmacy services; further,

To advocate that health insurers <u>healthcare payers</u> seek to optimize continuity of care in their design of benefit plans.

During the Council's June 2019 call, healthcare reform was slated as a topic for Policy Week discussion. Healthcare reform, which includes the entire spectrum of policy proposals from repeal of the Affordable Care Act to the creation of a public option (e.g., Medicare for All), continues to be a political hot topic. Thus, the Council undertook a review of relevant policies to ensure that ASHP can advocate for, and respond to, health reform proposals that impact pharmacy practice and patient care.

To center the discussion, the Council reviewed relevant policies as well as ASHP's Principles of Healthcare Reform. The Council then conducted a mini gap analysis of federal policy proposals since 2017, when the Principles were drafted, to determine if any policies were needed to address new developments. After talking through some recent proposals, including Medicare for All, the Council was not comfortable crafting policy responsive to any specific proposal. Instead, they determined that a flexible policy focused on coverage strength and patient access protections would be more effective.

Rather than drafting an entirely new policy, the Council reworked policy 1001, Health Insurance Coverage for U.S. Residents, which was up for sunset review. The new language in the proposed policy is designed to emphasize both access to, and affordability of, coverage. The Council also recommended updates to the policy's rationale. Specifically, the Council suggested the rationale note that the policy applies to all health insurance coverage and state that the "cost-effectiveness" of the language is meant to apply to both patients and systems (e.g., patients should pay for meaningful coverage and systems shouldn't have to pay for unnecessary interventions, etc.). Finally, the Council expressed concern as to whether the title should refer to U.S. residents or whether it should be more general (i.e., "Access to Health Insurance Coverage").



2. Care-Commensurate Reimbursement

- To advocate that reimbursement for healthcare services be commensurate with the
- level of care provided, based on the needs of the patient.

Rationale

As a means to reduce costs for federal programs, the Centers for Medicare & Medicaid Services (CMS) has been aggressively expanding efforts to reduce reimbursement at certain sites of care. Specifically, CMS has cut reimbursement for care services provided at hospital outpatient departments to match the rate paid physicians' offices. CMS refers to this policy as "site-neutral payment." On the basis of site neutrality, CMS also extended cuts to hospital reimbursement for drugs purchased under the 340B drug discount program to hospital outpatient departments. Private payers have also sought to impose site-neutral payment policies.

Reimbursement for services should reflect unique factors associated with a site of care. Hospital outpatient departments are held to higher quality standards with more oversight than what is often required for alternate sites of care. In addition to the Medicare Conditions of Participation, hospital outpatient departments must meet accreditation, United States Pharmacopeia (USP), and even Food and Drug Administration requirements. These standards result in high-quality patient care, but at a higher cost than what can be accomplished without the oversight.

Patients may also derive benefits from receiving care at a hospital outpatient department. Hospital care delivery models are crafted to ensure that patients receive the highest quality care possible. For hospitals that belong to an accountable care organization or are otherwise part of an integrated network, seeing patients at the outpatient department allows providers to better coordinate care, resulting in improved patient outcomes. Care provided in this setting is often highly complex and complementary to acute care that the patient receives from the hospital. Drastic cuts to hospital outpatient reimbursement could endanger the long-term viability of these care delivery models – if services are cut or outpatient departments are closed, patient access will suffer.

Background

The Council discussed this issue against a backdrop of ongoing CMS efforts (i.e., the CMS Hospital Outpatient Prospective Payment System proposed rule) to institute payment cuts in settings where ASHP members provide services. Although the Council recognized that the reimbursement in question might not be for medication in all cases, the clinical reimbursement that is the target for current cuts often supports pharmacist services. In theory, there was support for equal payment for equal services, but the Council agreed that the context of the services had the potential to impact quality and outcomes. Discussion also focused on the potential unanticipated consequences of reducing reimbursement, including potential incentives for certain settings to cherry-pick patients or to reduce emphasis on ambulatory care services. The Council also felt that reimbursement should differentiate between care settings unless all settings of care are held to the same regulatory and oversight standards, as



advocated in ASHP policy position 1914, Safe Medication Preparation, Compounding, and Administration in All Sites of Care.

3. Funding, Expertise, and Oversight of State Boards of Pharmacy

- To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply
- chain through coordination and cooperation of state boards of pharmacy and other
- state and federal agencies whose mission it is to protect the public health; further,
- 4 To advocate representation on state boards of pharmacy and related agencies by
- 5 pharmacists and pharmacy technicians; further,
- 6 To advocate that health systems are adequately represented on state boards of
- 7 pharmacy; further,
- 8 To advocate for dedicated funds for the exclusive use by state boards of pharmacy and
- 9 related agencies including funding for the training of state board of pharmacy
- inspectors and the implementation of adequate inspection schedules to ensure the
- effective oversight and regulation of pharmacy practice, the integrity of the
- pharmaceutical supply chain, and protection of the public; further,
- To advocate that inspections be performed only by pharmacists competent about the
- ¹⁴ applicable area of practice.

Note: This policy would supersede ASHP policy 1507.

Rationale

In recent years, the regulatory scope of boards of pharmacy has grown to address new and expanded scopes of practice and healthcare while fulfilling its mission of protecting the public health. In addition, coordination with federal agencies (e.g., Food and Drug Administration, Drug Enforcement Administration) and related state agencies add to the complexity of a state board's mission. With this expanded scope and mission comes the need for additional resources, both financial and human. Specific knowledge acquired by pharmacists and pharmacy technicians is essential to the safe regulation of practice. Thus, inspectors need to have that knowledge and training in order to assure the health and safety of the public.

Background

The Council reviewed ASHP policy 1507, Funding, Expertise, and Oversight of State Boards of Pharmacy, as part of sunset review and voted to recommend amending it as follows to simplify the language related to health-system representation on state boards of pharmacy (<u>underscore</u> indicates new text; strikethrough indicates deletions):

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply



chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate adequate-representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians are knowledgeable about who represent various areas of pharmacy practice (e.g., hospitals, health systems, clinics, and nontraditional settings) to ensure appropriate oversight; further,

To advocate that health systems are adequately represented on state boards of pharmacy; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,

To advocate that inspections be performed only by pharmacists competent about the applicable area of practice.

4. Dispensing by Nonpharmacists and Nonprescribers

- 1 To reaffirm the position that to ensure optimal patient outcomes all medication
- dispensing functions must be performed by, or under the supervision of, a pharmacist;
- 3 further,
- 4 To reaffirm the position that any relationships that are established between a
- 5 pharmacist and other individuals in order to carry out the dispensing function should
- 6 preserve the role of the pharmacist in (a) maintaining appropriate patient protection
- and safety, (b) complying with regulatory and legal requirements, and (c) providing
- 8 individualized patient care; further,
- To advocate that all medication dispensing be held to the same regulatory standards
- that apply to dispensing by a pharmacist; further,
- 11 To urge pharmacists to assume a leadership role in medication dispensing in all settings
- to ensure adherence to best practices.

Note: This policy would supersede ASHP policy 0010.

Rationale

The Council recognizes the reality of limited pharmacist availability and lack of comprehensive



pharmacy services in many settings, including public health clinics, rural and urban outreach clinics, and hospital emergency departments. However, the Council believes that responsibility and services of pharmacists are critical to safe medication use and that all dispensing should meet the same standards that apply to pharmacies and pharmacists. The Council believes that the current ASHP Minimum Standard for Pharmaceutical Services in Ambulatory Care is explicit and pertinent to the practice of dispensing by nonpharmacists and nonprescribers. The Council also noted that this type of drug delivery and dispensing arrangement does not constitute collaborative drug therapy management as defined in ASHP policy 9903.

Background

The Council reviewed ASHP policy 0010, Dispensing by Nonpharmacists and Nonprescribers, as part of sunset review and voted to recommend amending it as follows to strengthen the primacy of pharmacists in dispensing functions and to emphasize that patients are at risk when pharmacists do not maintain oversight of dispensing (<u>underscore</u> indicates new text):

To reaffirm the position that <u>to ensure optimal patient outcomes</u> all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,

To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient protection and safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing be held to the same regulatory standards that apply to dispensing by a pharmacist; further,

To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

5. New Categories of Licensed Pharmacy Personnel

To oppose the creation of new categories of licensed pharmacy personnel.

Rationale

State efforts to introduce a "pharmacist assistant" category conflict with longstanding ASHP efforts to support the professional growth of licensed or registered pharmacy technicians. Pursuant to these state proposals, pharmacists could delegate a number of activities that fall under the purview of their practice to the pharmacist assistant, such as receiving telephone calls, prescriptions, tech-check-tech, etc. In effect, this would create another midlevel provider in the pharmacy. Not only would this create confusion regarding terminology and job roles, it



would undermine ASHP's work to professionalize the technician role. The policy should not be read as impeding the use of current licensed personnel, including technicians and students.

Background

This issue arose after several states (e.g., New Hampshire, Ohio) introduced laws allowing the creation of a "pharmacist assistant." The Council discussed the background of the pharmacist assistant term, including the proposed role the pharmacist assistant would fill in practice. Discussion then turned to how the pharmacist assistant role would intersect with that of the pharmacy technician and lead to potential confusion related to different roles of pharmacy technicians that already exist. For instance, the intent by the laws in New Hampshire and Ohio was to shift non-clinical tasks to the pharmacist assistant. However, the law does not specify requirements for licensure or outline scope of practice, but instead instructs that the board of pharmacy develop rules to address them, which may or may not be consistent with pharmacy technician professional standards currently in place. Further, the pharmacist assistant, rather than the supervising pharmacist, will be accountable to the board of pharmacy for tasks performed within the pharmacist assistant's allowed scope of practice. Janet Silvester joined the Council to provide additional relevant details from the Consensus Conference of 2018 and the Pharmacy Technician Certification Board (PTCB) job analysis. The Council questioned the need for any new midlevel role and reinforced the importance of the pharmacy technician. The Council noted that the statement was not meant to in any way impede the use of current licensed personnel, including pharmacy technicians and students.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing <u>ASHP policies</u>, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Pharmacist Participation in Health Policy Development (1501)
- Pharmacist Recognition as a Healthcare Provider (1502)
- Expedited Pathways for FDA Drug Approval (1411)
- Medicare Prescription Drug Benefit (0813)
- Medication Therapy Management (1005)
- FDA Authority on Recalls (1003)
- FDA's Public Health Mission (0012)
- Nonproprietary Naming of Biological Products (1535)
- Patient Adherence Programs as Part of Health Insurance Coverage (1504)
- Statutory Protection for Medication-Error Reporting (1505)
- Regulation of Home Medical Equipment Medication Products and Devices (1007)



Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

Drug Pricing Recommendation

The Council voted to explore options for having ASHP convene a workshop of pharmacists with relevant expertise to examine proposed drug pricing policy solutions and create a report with policy recommendations.

During discussions regarding drug pricing proposals related to healthcare reform and site neutrality, the Council felt that even with the background reading, the ramifications and parameters of the various policies (e.g., the International Pricing Index Model) remained unclear. An ASHP report breaking down various drug pricing proposals could be used to inform future policymaking and advocacy on the topic.

Impact of Tariffs on U.S. Drug Supply

The Council discussed a recommendation to consider policy related to the impact of tariffs on the national drug supply, particularly active pharmaceutical ingredient (API) produced in China. Although the Council recognized the potential impact of tariffs on pricing and availability of finished pharmaceuticals, they felt that our current policies on drug pricing and shortages



would be sufficient to address the issue. Further, the Council was concerned that policy specific to tariffs would be perceived as overtly political and potentially divisive.

Pharmaceutical Quality

Although the Council had a robust discussion on pharmaceutical manufacturing quality, which arose from concerns about oversight of foreign manufacturing of generics, the Council did not propose new policy on the topic. The Council considered our current quality-related policies and deemed them robust enough to cover a range of quality issues. However, the Council did indicate that they have ongoing concerns related to the consistency of inspections of facilities as well as the application of the FDA's quality ratings program. The Council recommended that the Council on Pharmacy Management review policy 1602, Drug Product Supply Chain Integrity, to determine whether it should include stronger language regarding inspections. Further, the Council suggested that ASHP should create goals related to manufacturing quality and work them into a longer-term advocacy strategy.



COUNCIL ON THERAPEUTICS POLICY RECOMMENDATIONS

The Council on Therapeutics is concerned with ASHP professional policies related to medication therapy. Within the Council's purview are (1) the benefits and risks of drug products, (2) evidence-based use of medicines, (3) the application of drug information in practice, and (4) related matters.

Nish Kasbekar, Board Liaison

Council Members

Snehal Bhatt, Chair (Massachusetts)
Christi Jen, Vice Chair (Arizona)
Sarah Anderson (Colorado)
Amie Blaszczyk (Texas)
Rena Gosser (Washington)
Cyrine Haidar (Tennessee)
Calvin Ice (Michigan)
Matthew Kostoff (Ohio)
Wesley Kufel, New Practitioner (New York)
H. Henry Le, Student (Oregon)
Andrew Mays (Mississippi)
Carolyn Oxencis (Wisconsin)
Vicki Basalyga, Secretary

1. Safety and Efficacy of Compounded Topical Formulations

- To advocate for the development of processes that would ensure potency, quality, and
- standardization of compounded topical formulations; further,
- 3 To advocate that public and private entities establish a process to evaluate and regulate
- 4 the safety, efficacy, and composition of compounded topical formulations; further,
- 5 To advocate that public and private payers and healthcare providers collaborate to
- 6 create standardized and efficient methods for authorizing payment for medically
- 7 necessary compounded topical formulations; further,
- 8 To encourage hospitals and health systems to develop policies and procedures to guide
- 9 clinicians in making informed decisions regarding the prescribing and use of
- compounded topical formulations; further,
- To encourage pharmacists to take a leadership role in developing and providing
- education on the safety and efficacy of compounded topical formulations to providers
- ¹³ and consumers.



Rationale

Compounded topical formulations are meant to be customized for individuals whose needs cannot be met by commercially available drugs. Unlike the drugs made by conventional manufacturers that require Food and Drug Administration (FDA) approval, compounded drugs such as various topical formulations are not evaluated by the FDA for safety, effectiveness, or quality, and many are exempt from the new-drug approval process, current good manufacturing practice, and other FDA requirements. In addition, quality standards for compounded drugs are generally lower than those for FDA-approved drugs; therefore, compounded drugs can pose increased safety risks (e.g., being contaminated or having the wrong potency) or lack efficacy.

Because some drugs do have FDA approval for topical application, clinicians and patients may not be aware of potential safety risks or potential lack of effectiveness associated with certain ingredients and combinations of ingredients in compounded topical pain creams. When these agents are compounded, at least one of the ingredients is an active ingredient in an FDA-approved topical pain cream (e.g., lidocaine), while the remaining ingredients may be active ingredients in drugs approved by the FDA for non-topical administration to treat non-pain-related indications (e.g., antidepressants, anticonvulsants, antivirals, narcotics). In addition, the literature supporting the use of the additional agents outside their normal vehicle of administration is often not well designed and are not sufficiently powered to demonstrate efficacy. A study published by the U.S. Department of Defense found that these combination-compounded pain creams were no better than placebo creams, and with their higher costs, which had escalated to cost of \$6 million per day, should no longer be used.

Issues of fraud are also well known with compounded topical formulations. In August 2018, the Department of Health and Human Services Office of Inspector General (OIG) found that from 2006 to 2015, spending for these drugs increased 625%, and spending for compounded topical drugs—such as creams, gels, and ointments—grew at an even faster pace. Medicare Part D sponsors cover these drugs under certain circumstances. The OIG also found that Part D spending for compounded topical drugs increased 2353% from 2010 to 2016, rising from \$13.2 million to \$323.5 million. Much of this growth occurred from 2014 to 2016, when spending increased by more than \$200 million and raised concerns that the drugs that were billed to Part D were not always dispensed or medically necessary. Upon investigation, the OIG found that many of the parties charging Part D were located in a handful cities, with thousands of prescriptions written by a single provider and filled by a limited number of pharmacies. This led HHS to conclude that the prescribers may not have had legitimate doctor-patient relationships with the beneficiaries.

Background

The Council discussed the increase in prevalence of compounded topical agents now being seen in hospitals and health-systems, particularly in long-term care facilities. Council members noted that there is a notable lack of standardization in the creation of these formulations, often to the point where some providers have developed their own "brand" of topical formulation, with ingredients and strengths that may have evidenced-based



foundation. Council members also expressed concerns about safety and efficacy, as pharmacokinetic and pharmacodynamics data are not known with these agents, which could put patients at high risk for adverse events, particularly the elderly, who use these products most frequently. Council members also shared experiences in which colleagues were arrested, fined, and jailed as a part of fraud schemes involving compounded topical formulations. Finally, the Council expressed concerns surrounding questionable evidence on safety and efficacy, concerns around USP Chapter 795 compounding, and undermining the use of legitimate topical compounds that have evidence for use (e.g., estrogen for fertility).

2. Postmarketing Studies

- To advocate that Congress grant the Food and Drug Administration (FDA) authority to
- require the manufacturer of an approved drug product or licensed biologic product to
- 3 conduct postmarketing studies on the safety of the product when the agency deems it
- 4 to be in the public interest and to require additional labeling or withdrawal of the
- 5 product on the basis of a review of postmarketing studies; further,
- To advocate that Congress provide adequate funding to FDA and other agencies to fulfill
- this expanded mission related to postmarketing surveillance and studies; further,
- 8 To advocate that such studies compare a particular approved drug product or licensed
- 9 biologic product with (as appropriate) other approved drug products, licensed biologic
- products, medical devices, or procedures used to treat specific diseases; further,
- To advocate expansion of studies of approved drug products or licensed biologic
- products to improve safety and therapeutic outcomes and promote cost-effective use;
- 13 further,
- To encourage impartial private-sector entities to also conduct such studies.

Note: This policy would supersede ASHP policies 1004 and 0515.

Rationale

Pharmacists, other members of the healthcare team, patients, and private and public payers need objective, authoritative, and reliable evidence to make the best treatment decisions. Since the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Agency for Healthcare Research and Quality (AHRQ) has been tasked with studying the outcomes, comparative clinical effectiveness, and appropriateness of healthcare items and services. For such research to contribute to the practice of evidence-based patient care, good clinical decision-making, and rational drug use, AHRQ must evaluate devices, invasive procedures, and prescription and nonprescription medications, including both labeled and unlabeled uses of prescription drugs. Since prescription drugs represent a significant and growing portion of healthcare costs, the need for such research is increasingly important.



Although impartial private sector entities can supplement the research efforts of government agencies such as AHRQ, only the federal government has the ability to support such independent research, provide oversight to safeguard the integrity of the research process, and disseminate the findings.

Furthermore, to ensure safety, the Food and Drug Administration (FDA) has several requirements for manufacturers and programs in place monitor postmarket adverse events. These requirements and programs include the Division of Medication Error Prevention and Analysis, which is responsible for monitoring and preventing medication errors related to the naming, labeling, packaging, and design for CDER-regulated drugs and therapeutic biological products; the Risk Evaluation and Mitigation Strategy (REMS) program, which is designed to help reduce the occurrence and severity of certain serious risks; by informing and supporting the execution of the safe use conditions described in the medication's FDA-approved prescribing information; the Safe Use Initiative, a program that aims reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use. Other programs include the FDA Adverse Event Reporting System (FAERS), which is a database that contains adverse event reports, medication error reports, and product quality complaints resulting in adverse events that were submitted to FDA, and MedWatch, the FDA Safety Information and Adverse Event Reporting Program, which permits voluntary reporting by consumers and healthcare professionals and mandatory reporting for regulated industry and user facilities. Additionally, the FDA requires that adverse drug events (ADEs) must be reported in accordance with the requirements of 21 CFR 310.305 and 314.80, which require three types of ADE reports: (1) 15-day reports of serious, unlabeled events; (2) 15-day narrative increased frequency reports of serious, labeled events; and (3) periodic reports.

Background

The Council reviewed ASHP policies 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, and 0515, Postmarketing Safety Studies, as a part of sunset review and concluded that, although there is still a need for both of these policies, the essential elements should be consolidated into a single new policy. ASHP policy 0515, Postmarketing Safety Studies, reads:

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA to fulfill this expanded mission related to postmarketing surveillance.

ASHP policy 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, reads:



To advocate expansion of comparative clinical and pharmacoeconomic studies on the effectiveness, safety, and cost comparison of marketed medications in order to improve therapeutic outcomes and promote cost-effective medication use; further,

To advocate that such studies compare a particular medication with (as appropriate) other medications, medical devices, or procedures used to treat specific diseases; further,

To advocate adequate funding for the Agency for Healthcare Research and Quality and other federal agencies to carry out such studies; further,

To encourage impartial private-sector entities to also conduct such studies.

The Council voted to recommend amending the two policies as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA <u>and other agencies</u> to fulfill this expanded mission related to postmarketing surveillance <u>and studies</u>; <u>further</u>,

[CLAUSE MOVED] To advocate that such studies compare a particular medication approved drug product or licensed biologic product with (as appropriate) other medications approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

To advocate expansion of comparative clinical and pharmacoeconomic studies of approved drug products or licensed biologic products on the effectiveness, safety, and cost comparison of marketed medications to improve safety and therapeutic outcomes and promote cost-effective use; further,

To advocate adequate funding for the Agency for Healthcare Research and Quality and other federal agencies to carry out such studies; further,

To encourage impartial private-sector entities to also conduct such studies.



3. Gabapentin as a Controlled Substance

- To advocate that the Drug Enforcement Administration reschedule gabapentin to
- 2 Schedule V due to its low potential for abuse and patient harm.

Rationale

Gabapentin is a structural analog of gamma-aminobutyric acid that is approved by the Food and Drug Administration (FDA) for post-herpetic neuralgia and as an adjunctive therapy for partial seizures. Gabapentin has been identified as an opportunistic drug of abuse which, when used in conjunction with other medications, particularly opioids, may result in serious adverse events such as respiratory depression and even death. Gabapentin is used due to its low cost, classification as a noncontrolled substance, and increasing rates of on- and off-label prescribing attributable to clinicians' desire for an alternative to opioids for pain management. In the U.S., gabapentin is and remains a noncontrolled substance at the federal level despite evidence suggestive of diversion and abuse with opioids. Most recently, several states have made an effort to combat the diversion and abuse of gabapentin by examining various regulatory approaches, such as reclassification of gabapentin as controlled substance or mandating the reporting of the prescribing and/or dispensing of gabapentin to a state-level prescription drug monitoring programs (PDMPs). As recently as April 2019, the United Kingdom reclassified gabapentin as a Class C controlled substance, which required similar dispensing and monitoring as controlled substances in the U.S., due to the increase in abuse they have seen in this drug.

As defined by the Drug Enforcement Administration (DEA), Schedule V controlled substances "are defined as drugs with lower potential for abuse than Schedule IV" substances. Schedule IV substances "are defined as drugs with a low potential for abuse and low risk of dependence." Recent data from multiple sources have shown a significant increase in gabapentin misuse, abuse, and diversion over the past 10 years, and one study found that 22% of a sample of 162 opioid-dependent patients had a prescription for gabapentin, of which 40% indicated they used more than prescribed to augment and enhance their opioid experiences.

The criteria used by DEA to determine whether to control or reschedule a drug include (a) the drug's actual or relative potential for abuse; (b) scientific evidence of its pharmacological effect, if known; (c) the state of current scientific knowledge regarding the abuse of the drug or other substance; (d) its history or current pattern of abuse; (e) the scope, duration, and significance of abuse; (f) what, if any, risk there is to public health; (g) its psychic or physiological dependence liability; and (e) whether the substance is a precursor of a substance already controlled under the law. Based on an assessment using these criteria, gabapentin is similar to other controlled substances found in Schedule V and should therefore be assigned to Schedule V. Because some states have already taken steps to reschedule gabapentin as Schedule V or have added it to their PDMPs, the DEA should take steps to change the schedule status of gabapentin to ensure continuity of care and monitoring.

While it is difficult to predict the impact rescheduling may have on abuse, the current extent of abuse is likely exacerbated by easy access to and excessive supply of these therapies. However, the potential public health benefit of rescheduling must be weighed against concerns



about restricting patients' access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. In balancing these concerns, it should be noted that increased control of drugs with abuse potential is in the best interests of patients and public health. DEA and other stakeholders should monitor the impact of this scheduling change on patient access and practice, as well as monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

Background

The Council discussed the need to reschedule gabapentin from a nonscheduled drug to Schedule V under the Controlled Substance Act. The Council's assessment included the review of the DEA criteria for drugs in Schedule V, the schedule status of the structurally similar drug pregabalin, and the reports from entities concerning the extent of abuse and patient harm. The Council discussed the necessity of the rescheduling of gabapentin to a Schedule V designation. Council members shared that they often see inappropriate prescribing in the outpatient setting in both the dose and frequency, which they believe may also be contributing to the cycle of abuse, as well as lack of an antidote. Furthermore, the Council discussed their concerns about patient access, noting that although the number of states making such a schedule change is increasing, scheduling is inconsistent across the U.S., which could lead to access and diversion issues. The Council believed that encouraging the DEA to change gabapentin's schedule status would permit a uniform approach to monitoring and metrics.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing <u>ASHP policies</u>, the following policy was reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue this policy.)

Generic Substitution of Narrow Therapeutic Index Drugs (0817)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in



November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

ASHP Statement on Over-The-Counter Availability of Statins

The Council reviewed the ASHP Statement on Over-The-Counter Availability of Statins as part of sunset review. The Council believes that there is still a need for this statement but that is should be updated, since it has remained unchanged since drafted and approved in 2005. The Council recommends that content matter experts update this statement to include considerations for newer classes of statins; pharmacogenomics considerations and other areas not articulated in the current statement, including concerns for duplicate therapy; picking the most appropriate statin; omission from medication histories, as many patients do not consider over-the-counter medications as a part of their regimen; the Affordable Care Act increasing access to statins; and the role of statins as a significant part of quality measures now seen in healthcare. The Council agreed that while the updates are written, the statement should remain accessible and notice should be posted to indicate that that statement is currently under revision.

Continuous and Extended Interval Antibiotic Dosing

The Council discussed the practices of extending interval, continuous, and intravenous (IV) push administration of antibiotics and their role in practice. The Council reviewed how these treatment strategies, particularly extended internal and continuous infusions, have shown to increase the time an antimicrobial's concentrations in the blood, mostly beta-lactams, are above the minimum inhibitory concentration, and the impact this has on critically ill patients, patients with impaired renal function, and outpatient strategies. The Council also discussed how new beta-lactams are only being studied as prolonged infusions. Members shared their institutions' practices, which were variable across the country and depended on the antimicrobial. The Council also discussed the strategies that were employed during the small volume parenteral shortage, which consisted of administration of antimicrobials over IV push. The Council considered the data and operational considerations around these strategies and



believed that the best approach for ASHP would be to provide education on the impact of these administration approaches on morbidity, mortality, cost savings, and operational considerations.

Clinical Utility of Drug-Specific Reversal Agents for Direct Oral Anticoagulants

The Council discussed the current clinical, cost, and ethical issues surrounding the use of drugspecific reversal agents for direct oral anticoagulants. During the discussion, it was noted that most large academic medical centers will carry most of the drug-specific reversal agents, as the cost is not a barrier, whereas small and rural institutions will carry only one brand, use means of reversal that were available prior to the development of these drug-specific agents, or transport the patient to an institution that carries the agents. The Council also noted the need for research on dosing strategies, as these drug-specific reversal agents can be administered on a fixed-dose or weight-based strategy, and approaches vary widely across the country. The Council also discussed the pressure of keeping multiple agents on formulary, as practitioners are prescribing the direct oral anticoagulants more frequently and are assuring patients that all hospitals will have the required reversal agent, and the need for protocol-based management if the agent is on formulary, as use should be restricted to certain clinical cases. When reviewing existing policies, they believed that ASHP policy 1703, Pharmacist's Leadership Role in Anticoagulation Therapy Management, addressed most of the concerns discussed but was missing the reversal component in the clauses and therefore recommended that the policy be updated to reflect this.

Safety and Clinical Considerations for IV Fluid Lounges and Blood Bars

A recent practice emerging on the consumer side of healthcare is the option to receive IV fluids or blood transfusions when it's not considered medically necessary or specifically recommended as part of an established doctor-patient relationship. These sites often advertise their services as options for recovering from jetlag, hangovers, or food poisoning, or to improve a person's appearance, and treatments are paid for out of pocket. The Federal Trade Commission has already investigated several of these companies that have claimed to be able to treat a variety of maladies and cited them for these infractions. Council members discussed the impact these facilities have on patient safety and hospitals and health systems, including cases of patient death due to sepsis, driving up the price of drugs in shortage, lack of medications and ingredients essential to patients who require them, and potential violations of USP Chapter 797. Council members also cited knowledge of other organizations, including A.S.P.E.N. and the Academy of Dietetics, who also view these sites as a threat to patient safety and well-being. Interestingly, many Council members were unaware how prolific these IV lounges where within their communities and suggested that ASHP provide education on the rising prevalence and risk these unique operations pose. Ultimately, the Council did not feel strongly that this warrants creation of an ASHP policy but suggested ASHP should collaborate with outside organizations such as A.S.P.E.N. and the Academy of Dietetics to write a statement or commentary on the impact these lounges are having on patient care to reach a broader audience and increase visibility of the potential dangers of this growing niche industry.



Intravenous Lidocaine for Pain Management

Lidocaine is a is a class 1 B antiarrhythmic agent, which is mainly used for the treatment of ventricular arrhythmias and most commonly used as a local anesthetic in the outpatient setting. Intravenous (IV) lidocaine has become an increasingly popular alternative for acute pain management in post-operative settings, cancer pain management, and as a treatment strategy in the emergency department, as practitioners seek alternatives to opioids, particularly as it is an agent used in the alternatives to opioids (ALTO) approach to pain management. The Council discussed the patient safety and practice issues around using lidocaine for pain management, including the following:

- different dosing strategies (it is infused as mg/min as an antiarrhythmic but mg/kg/hr for pain management),
- the need for cardiac monitoring,
- lack of data for safety and efficacy after 24 hours, and
- electrolyte and serum monitoring, and no conclusive correlation between serum levels and pain relief.

Despite these potential barriers, there is still promise that lidocaine could be an appropriate medication in certain clinical situations. Therefore, the Council recommends that there be more information available to pharmacists, including education, resources, and potentially a review article on the available safety, efficacy, and operational considerations for using this agent for the management of pain.



COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATION

The Council on Education and Workforce Development is concerned with ASHP professional policies, related to the quality and quantity of pharmacy practitioners. Within the Council's purview are (1) student education, (2) postgraduate education and training, (3) specialization, (4) assessment and maintenance of competence, (5) credentialing, (6) balance between workforce supply and demand, (7) development of technicians, and (8) related matters.

Paul C. Walker, Board Liaison

Council Members

Seena Haines, Chair (Mississippi)
Garrett Schramm, Vice Chair
(Minnesota)
Angela Bingham (Pennsylvania)
Christopher Edwards (Arizona)
David Gregory (Tennessee)
Chelsea Gresham, New
Practitioner (West Virginia)
Carol Heunisch (Illinois)
Jesse Hogue (Michigan)
Norman Hooten (Florida)
Denise Kelley (Florida)
Ann Lloyd (Oklahoma)
Jenna Summerlin, Student, (Tennessee)
Erika Thomas, Secretary

1. Residency Training for Pharmacists Who Provide Direct Patient Care

- To recognize that optimal direct patient care by a pharmacist requires the development
- of clinical judgment, which can be acquired only through experience and reflection on
- 3 that experience; further,
- 4 Pharmacists who provide direct patient care should have completed an ASHP-accredited
- residency or have attained comparable skills through practice experience; further,
- 6 To support the position that the completion of an ASHP-accredited postgraduate-year-
- one residency be required for all new college or school of pharmacy graduates who will
- 8 be providing direct patient care.

Note: This policy would supersede ASHP policies 0701 and 0005.

Rationale

Pharmacists who engage in direct patient care can improve patient outcomes and significantly decrease the overall costs of the healthcare system. Completion of a postgraduate pharmacy residency enables a pharmacist to maximize the provision of these direct patient care services.



The use of well-trained pharmacy technicians and technological advances will minimize pharmacists' dispensing roles. Based on the assumption that in the next 20-30 years most pharmacists will be providing direct patient care, it is incumbent upon the pharmacy profession to ensure that pharmacists are in a position to make the most effective interventions when selecting, modifying, and monitoring patients' drug therapy regimens.

Pharmacy students who graduate meet the minimum competency requirements based on pharmacy licensing examinations; however, pharmacists who have completed a residency are better equipped to provide direct patient care due to advanced training based on repetitive practice, preceptor guidance, and the additional interdisciplinary training they receive. This direction is consistent with ASHP's Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems.

Similar to the medical model in which medical school graduates complete a residency that allows for the standardization of physician training and the attainment of an appropriate level of competency, the profession of pharmacy would benefit from a similar standardization of training. The value of pharmacy residency programs has been demonstrated over time and has stimulated a significant increase in accredited residency programs as well as employer demand for residency-trained pharmacists. An increasing number of pharmacy graduates are completing one or two years of residency training after graduating in order to bolster their clinical skills and develop clinical judgement, which is acquired only through experience and reflection on that experience.

The number of PGY1 residencies continues to grow with the number of available residencies in the U.S. is now nearly 2600 programs. The growth in the number of pharmacy school graduates has begun to plateau while PGY1 residency positions has grown 11% in the last three years.

Background

The Council reviewed ASHP policy 0005, Residency Training for Pharmacists Who Provide Direct Patient Care, and ASHP policy 0701, Requirement for a Residency, as part of sunset review and voted to recommend consolidating the two policies and amending them as follows (<u>underscore</u> indicates new text; <u>strikethrough</u> indicates deletions; first two clauses are from policy 0005 and the final one is from policy 0701):

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that experience; further,

Establish as a goal that Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position that by the year 2020, the completion of an ASHP-accredited postgraduate-year-one residency should be a requirement required for all new college or school of pharmacy graduates who will be providing direct patient care.



Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing <u>ASHP policies</u>, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Communication Among Health-System Pharmacy Practitioners, Patients, and Other Healthcare Providers (0510)
- Employment Classification and Duty Hours of Pharmacy Residents (1008)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

ASHP Statement on Professionalism

The Council reviewed the current ASHP Statement on Professionalism, approved by the ASHP Board of Directors in 2007, and discussed the relevance of the document in light of



contemporary practice. Council members believed that the statement is still necessary and relevant, but suggested that the scope of the statement be expanded to include the pharmacy workforce. Members also discussed how social media is prevalent in practice and our personal lives and should be addressed in the statement. As contemporary practice extends patient care beyond the hospital and into areas such as ambulatory care, transitions of care, and other areas, the Council felt that these new practices should be considered when updating the statement. Additional facets of contemporary professionalism that the Council felt should be addressed include the concept of continuous professional development, credentialing and privileging, and board certification. The Council also discussed how professionalism is an important characteristic of leadership and as pharmacists and pharmacy technicians continue to evolve into leadership roles, both formal and informal roles, professionalism is an important foundation for the pharmacy workforce. A writing group will develop an updated statement and bring the statement back to Council.

Mental Health Resources and Training Programs

Council discussed the fact that one in five Americans suffers from a mental illness or substance use disorder. Members also agreed that recognizing mental health and substance use challenges can be difficult, which is why it is so important for everyone, including pharmacists, to understand the warning signs and risk factors. Mental health resources available for the general public as well as healthcare practitioner-level training resources were discussed. Council acknowledged that mental health training and awareness is an important component of ASHP policy 1825, Clinician Well-being and Resilience that Council drafted in 2018, as well as the ASHP Clinician Well-Being and Resilience Initiative. The fact that the level of mental health training in the pharmacy curriculum varies widely was addressed, but overall the Council felt that most student pharmacists currently have minimal education in this area. However, many schools and colleges of pharmacy are currently developing further pharmacy-specific education on mental health based on programs such as the Mental Health First Aid program offered through the National Council for Behavioral Health. Council members also acknowledged that pharmacists are in a unique position to recognize selected warning signs of mental health issues based on the patient's medication therapy and that training pharmacists on targeted patient education on mental health is an important component of effective patient counseling. Sharing of best practices in this area is also important. Further, making additional resources available on the Workforce Well-Being and Resilience Resource Center and the State Affiliate Well-Being and Resilience Toolkit, will further disseminated this important information. The Council addressed this topic to determine the need for an ASHP policy advocating for mental health training and education for the pharmacy workforce. Members were in agreement that this issue is most appropriately addressed through education and raising awareness among the pharmacy workforce instead of a new policy. Members also felt that ASHP policy 1901, Suicide Awareness and Prevention, also advocates for education and training of the pharmacy workforce on mental health.

Pharmacists in the Gig Economy

The Council discussed the new roles for pharmacists as temporary or contract workers in the



"gig economy," which is becoming more commonplace due to smartphone technology. As stated in the 2014 National Pharmacist Workforce Survey, "the pharmacy profession currently has, and will continue to build, capacity for contributing to the U.S. healthcare system. However, as shifts in professional roles occur, deployment of capacity must meet the requirements of changing service models." Examples of contract work facilitated by digital platforms were reviewed. The Council discussed implications of new roles for these temporary or contract workers, including the following: educational training, professional training and redeployment, updates to practice acts and regulations, new documentation and billing systems, enhanced information exchange, collaborative practice models, infrastructure, technology, policy, and new business models. Council felt that with the increase in mail-order pharmacies and closing of community pharmacies (especially rural pharmacies), patients are further away from personal interaction with pharmacists, and the gig economy model has the potential to deploy pharmacists to meet with patients on demand. This could be especially beneficial in rural communities, where access to a pharmacist may not be available through primary or ambulatory care.

New models of temporary and contract work may provide an innovative model for expanding patient care and additional income to pharmacists. The Council will continue to monitor these new roles in the gig economy and the potential impact on the pharmacy workforce.

Essential Elements for Core Advanced Pharmacy Practice Experiences: Hospital and Health-System Pharmacy Essential Elements

The Council discussed the American Association of Colleges of Pharmacy (AACP) new Hospital/Health System (HS) Pharmacy Essential Elements and implications for hospital and health-system practice. In February 2015, the Accreditation Council for Pharmacy Education (ACPE) published the 2016 accreditation standards and key elements for professional programs in pharmacy leading to the doctor of pharmacy degree. The standards outlined principles for both the didactic and experiential curriculum. ACPE's standards focus on key elements that should be incorporated in experiential rotations to help students become practice-ready upon graduation. Although the hour allotment is specified, definitions of each of the required practice settings is not provided. Due to the lack of definitions regarding each required practice setting, inconsistencies have been found in how colleges and schools of pharmacy interpret the core advanced pharmacy practice experiences (APPEs). In an effort to bring uniformity to the expectations of student learning in each practice area, AACP formed a task force charged with developing a set of essential elements describing the minimum competencies for each setting. After the initial AACP task force draft in 2016, essential elements were approved for all practice settings, with the exception of the HS APPE. In 2019, the AACP task force finalized the essential elements for HS APPEs.

Council members discussed the HS APPE essential elements, taking into consideration the inpatient general medicine patient care APPE essential elements; the ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, which outlines critical pharmacy service elements that are essential to successful patient care outcomes; and the ASHP/ACPE Entry Level Competencies Needed for Pharmacy Practice in Hospital and Health Systems, which



describes the competencies needed for entry-level practice in hospitals and health systems and helps identify gaps in the readiness of new pharmacy graduates were also considered in the discussion. Council members acknowledged that the HS APPE essential elements were new and colleges and schools of pharmacy will be determining how this would be implemented. Council members also acknowledged the fact that residency programs may be impacted because some residents may require additional training in compounding sterile preparations since students may not have the necessary training or certification to compound sterile preparations upon graduation.

Recent Pharmacy Workforce-Related Survey Results

The Council discussed several recent pharmacy workforce-related survey results, including the AACP New Graduate Surveys, HRSA Allied Health Workforce Projections, 2016-2030: Pharmacists, and ASHP National Survey of Pharmacy Practice in Hospital Settings: Workforce—2018 to determine whether there are implications for ASHP policy.

Dr. Bradley-Baker provided Council with an update on the Pharmacy Career Information Center (PCIC) and the recent 2019 National Pharmacist Workforce Study - Preliminary Results of Main Survey.

The Council discussed the importance of communicating to ASHP members that the profession is changing and pharmacists need to be proactive about its future. The Council discussed how the profession should take this opportunity to highlight what pharmacists are trained to do and how we can continue to expand the scope of currently provided services. The Council also suggested that ASHP continue to explore collaborations with other organizations that advocate for expanded pharmacist participation in patient care.

Clinician Well-Being and Resilience – Residency Standards

The Council discussed incorporating the requirements for well-being and resilience into pharmacy residency standards and the issue of pharmacy residency preceptor resilience and well-being. Council has examined the issue of clinician well-being and resilience in the past and developed proposed policy for ASHP policy 1825, Clinician Well-Being and Resilience. The Accreditation Council for Graduate Medical Education (ACGME) recently incorporated requirements for clinician well-being and resilience into residency program requirements. The requirements emphasize that "psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician." As the ASHP Commission on Credentialing (COC) revises the standards for pharmacy residency programs, the issue of incorporating well-being and resilience into the standards is under discussion. In addition to considering embedding well-being and resilience into the residency standards, the COC will be considering other platforms, such as initiatives, ideas, and routines, which can be implemented in pharmacy residency programs to promote clinician well-being and resilience.

The discussion on the proposed addition of clinician well-being and resilience requirements into pharmacy residency standards included the possibility of expanding the effort to include preceptors and residency program directors. Council members provided examples of how organizations and departments are addressing this issue. For example, one program spends the last 20 minutes of each day discussing what went well that day and



another program covers available services during the resident on-boarding process. The Council agreed on the importance of identifying and educating residents and preceptors on available resources and signs of burnout before a crisis occurs. ASHP was encouraged to continue to provide resources and best practices on well-being and resilience to members. The Council discussion on this topic will be shared with the COC as they continue this discussion.

Pharmacists Role in Mitigating the Primary Care Physician Shortage

The Council examined the role that pharmacists, as direct care providers, can assume to incorporate pharmacists into primary care models of care to help address the shortage of primary care physicians. The Association of American Medical Colleges (AAMC) published an updated report in April 2019, Complexities of Physician Supply and Demand: Projections from 2017-2032, that projected a shortage of up to 122,000 physicians by the year 2032, including a shortfall of up to 55,200 primary care physicians. Population growth and aging are the most important contributing factors for increased demand in healthcare services. The shift from feefor-service to value-based care as part of the U.S. healthcare system transformation places an increased emphasis on population health initiatives that achieve the quadruple aim of including healthcare lowering costs, improving quality, and improving the patient and provider experience. Increases in chronic disease, mental health concerns, and the opioid epidemic have influenced the number of patients needing care, and improving access to care is a goal of the Affordable Care Act. Rural and underserved communities are particularly impacted by the primary care provider shortage, leading to health disparities and poorer outcomes.

Pharmacists are considered our nation's medication experts, and multiple organizations, including the National Governors' Association, the Patient Centered Primary Care Collaborative (PCPCC), and Get the Medications Right Institute, advocate for recognizing pharmacists as providers, embedding pharmacists into primary care practices, and creating financial sustainability for the provision of comprehensive medication management by pharmacists. ASHP has long championed the role of the pharmacist on interprofessional teams and the development of collaborative practice agreements, and served as a leader in developing best practices in ambulatory care. Pharmacists across the country provide a wide variety of services in interprofessional teams including but not limited to annual wellness visits, disease management, transitions of care, comprehensive medication management, immunizations, medication assistance, medication adherence programs, and many others.

In order to increase uptake of these models, ASHP developed the Ambulatory Care Self-Assessment as part of the Practice Advancement Initiative and support pharmacists and health systems with the development of innovative care models that increase access to care and improve patient care outcomes through the A3 Collaborative. Although pharmacists could improve patient care outcomes through the provision of direct patient care services, the AAMC report focuses primarily on the role that physician assistants and nurse practitioners play in mitigating the primary care physician shortage. As the nation grapples with how to care for an aging population and provide comprehensive, accessible, patient-centered care for a growing population, it is paramount that pharmacists are seen as a profession that can mitigate the primary care provider shortage. Continued collaboration with medical, physician assistant, and nurse practitioner professional organizations as well as groups such as Get the Medications Right Institute, the A3 Collaborative, PCPCC, the Centers for Medicare & Medicaid Services, and



others is warranted so that the profession of pharmacy is at the table when solutions to the primary care shortage are developed. Council discussed the fact that pharmacists working as primary care providers could be especially important in rural and underserved communities. As of today, individual states authorize pharmacists to offer certain healthcare services for patients, including immunizations, diabetes management, blood pressure screenings, and various routine checks. However, these services are not federally recognized, and there is no direct path for Medicare to reimburse for these services. This is a barrier to pharmacists providing primary care.

The Veterans Health Administration is a model of pharmacists providing primary care – practicing at the top of their licenses and scopes of practice, demonstrating impact for quality care and improving access to care for patients. Council members felt that it was imperative that the workforce, new graduates and current practitioners, continue to prepare to provide primary care now. The need for continued provider status advocacy on the state and national level is imperative. The ASHP Statement on the Pharmacist's Role in Primary Care will be updated and brought back to Council for approval.

Updates on ASHP Residencies, Well-being and Resilience Initiative, and Preceptor Resources

The Council was provided with updates on topics from previous Council discussions. During the update on residences, it was announced that the number of residency program has exceeded 2500 programs. Although the number of programs continues to grow, PGY2 residency growth exceeds PGY1 growth. There has been progress in requiring accredited education for licensure of technicians with NABP, and New Hampshire is now looking at this issue. An update on ASHP's Workforce Well-Being and Resilience initiative highlighted new milestones in the upcoming year, including a December 2019 Well-Being Collaborative, continued dedicated programming at ASHP national meetings, expanded Resource Center information for members, a membership-wide survey, and continued collaborations with the National Academy of Medicine. Finally, an update on the Section of Inpatient Care Practitioners Section Advisory Group on Pharmacy Practices Experiences Precepting's initial work on IPPE Preceptor resources was presented.

Credentialing, Privileging, and Competency Assessment

At its Policy Week 2019 meeting, the Council on Public Policy reviewed ASHP Policy 1907 on the suggestion of the ASHP House of Delegates and voted to recommend amending that policy. After reviewing the proposed amendments (provided below), the Council on Public Policy noted that ASHP policy 1415, Credentialing, Privileging, and Competency Assessment, contained very similar language and asked the Council on Education and Workforce Development to review the two policies (policy 1415 and the proposed revisions to policy 1907) for potential consolidation. The Council on Public Policy recommended amending policy 1907 to read as follows:

To recommend the use of credentialing and clinical privileging in a manner consistent with other healthcare professionals to assess a pharmacist's competence to engage in patient care services.



The Council on Education and Workforce Development reviewed the two policies and agreed that the two policies could be consolidated by revising policy 1415 as follows (<u>underscore</u> indicates new text; strikethrough indicates deleted text):

To support the use of post-licensure credentialing, privileging, and competency assessment to practice pharmacy as a direct patient care practitioner; further,

To recommend the use of post-licensure credentialing, privileging, and competency assessment in a manner consistent with other healthcare professionals to assess a pharmacist's competence to engage in patient care services; further,

To advocate that all post-licensure pharmacy credentialing programs meet the guiding principles established by the Council on Credentialing in Pharmacy; further,

To recognize that pharmacists are responsible for maintaining competency to practice in direct patient care.

The Council also noted that the Board of Directors and the House of Delegates had not yet had a chance to review and potentially amend the revised policy 1907, and agreed to defer action on consolidating the two policies until the Board and House of Delegates take action.

Council Review of ASHP Policy 1715, Collaborative Practice

On the suggestion of the Council on Public Policy, the Council reviewed ASHP policy 1715, Collaborative Practice, for potential consolidation with policy 1415. The Council concluded that the topics of the policies were substantially different and that consolidation would not be appropriate, so no action was taken.



COUNCIL ON PHARMACY MANAGEMENT POLICY RECOMMENDATIONS

The Council on Pharmacy Management is concerned with ASHP professional policies related to the leadership and management of pharmacy practice. Within the Council's purview are (1) development and deployment of resources, (2) fostering costeffective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.

Kristina L. Butler, Board Liaison (Oregon)

Council Members

Victoria Serrano Adams, Chair (California)
Staci Hermann, Vice Chair (New Hampshire)
Ashley Bowden, New Practitioner (Utah)
Daniel Dong (California)
Lynn Eschenbacher (Missouri)
Amanda Hays (Missouri)
Jessica Hill (New Jersey)
Rondell Jaggers (Georgia)
Trinh Le (North Carolina)
Bonnie Levin (Maryland)
Arpit Mehta (Pennsylvania)
Lyndsay Ryan, Student (New Mexico)
Eric Maroyka, Secretary

1. Pharmacist's Role in Health Insurance Benefit Design

- To advocate that pharmacy practice leaders collaborate with internal and external
- 2 partners who design, negotiate, and select their own organization's health plans and
- 3 pharmacy benefit management contracts to preserve the integrity of health-system
- 4 pharmacy operations.

Rationale

Pharmacy leadership should be directly involved in the selection of the health system's pharmacy benefit manager (PBM) servicing their employee's health plan, and the terms of that contract with that PBM. Employers typically look to balance value for the employee while attempting to control costs. As health systems evaluate and select plans, there may not always be due consideration given to the potential impact to that health system's pharmacy operations and financial solvency in servicing employees' prescriptions through the selected PBM. Aside from the safety and continuity of care implications to the patient if the health system's pharmacy is excluded from the employees' network, organizations may unknowingly undermine utilization of their outpatient cancer and infusion programs. Three PBMs control the majority of the PBM market, exerting heavy influence in costs, pharmacy participation, formulary, and prior authorization criteria. By including pharmacy leadership to help make a well-informed decision about selecting a servicing PBM for a health system, and the contract terms associated with that PBM (i.e., clinical and financial aspects), some of these unintended consequences could be avoided.



Background

Given the significance of the topics in the proposed policy for the responsibility for the care of patients and the fiscal solvency of hospitals and health systems, the Council recommended ASHP support education for pharmacy practice leaders on the key elements of this proposed policy. Consideration should be given to executive leader skills to ensure presence and leadership to influence employee health and pharmacy benefit design; how to conduct a formulary review in the 21st century, keeping the care continuum in mind; a pharmacy benefit management "boot camp" (i.e., economics of the business of pharmacy); and partnership with other pharmacy and nonpharmacy associations (e.g., Academy of Managed Care Pharmacy, American College of Healthcare Executives, Society for Human Resource Management, National Community Pharmacists Association). Additionally, ASHP should support research and develop educational resources for hospital executives, providers, and patients to address concerns about biosimilar formulary changes (e.g., safety concerns, interchangeability, emotional impact).

2. Preserving Patient Access to Pharmacy Services in Medically Underserved Areas

- To advocate for funding and innovative payment models to preserve patient access to
- acute and ambulatory care pharmacy services in rural and medically underserved areas;
- 3 further,
- 4 To support the use of telepharmacy to maintain pharmacy operations and pharmacist-
- 5 led comprehensive medication management that extend patient care services and
- 6 enhance continuity of care in rural and medically underserved areas; further,
- 7 To advocate that the advanced communication technologies required for telepharmacy
- 8 be available in rural and medically underserved areas; further,
- 9 To advocate for funding of loan forgiveness or incentive programs that recruit
- pharmacists and pharmacy technicians to practice in rural and medically underserved
- 11 areas.

Rationale

Increasing hospital closures are not a recent phenomenon – rural areas have been closing hospitals for decades. For instance, 140 rural hospitals closed between 1985 and 1988 after the implementation of Medicare's Inpatient Prospective Payment System. This payment model led to large Medicare losses and increased financial distress for many rural hospitals, ultimately resulting in numerous hospital closings.

Today, many rural hospitals are facing a similar fate. Nationally, 430 rural hospitals are at high financial risk due to low reimbursement rates and decreasing local populations. These factors make it difficult for hospitals to cover fixed costs, let alone remain up to date with



technological advances and emerging healthcare practices.

Since 2010, 99 hospitals in rural and medically underserved areas in the U.S. have closed. Between 2013 and 2017 alone, 64 rural hospitals closed, which is more than twice as many as the previous 5-year period. Hospital closures disproportionality affected rural hospitals in the South (64% of rural hospital closures) and are more prevalent in states that did not expand Medicaid coverage. It is estimated that hundreds more hospitals are at risk of closing; therefore, the impact of these closures on access to and continuity of care should be assessed.

Although hospital closures in rural areas have numerous consequences, reduced access to care for the populations served is the most obvious one. An analysis by the Medicare Payment Advisory Commission determined that one third of hospitals that have closed since 2013 are more than 20 miles from the next closest hospital. An issue brief published by The Kaiser Commission on Medicaid and the Uninsured found a major impact of hospital closure to be loss of access to emergency care in the community; more specifically, a lack of access for people with acute mental health or addiction treatment needs was found.

Other consequences of rural hospital closures are focused around accessibility of physicians and other healthcare providers. Regardless of hospital closures, rural communities commonly struggle to recruit and retain healthcare providers. Retention of these providers becomes increasingly difficult when a hospital closes due to providers relocating to an alternative hospital or clinic location. As a result, communities are often left without vital healthcare providers and exacerbate gaps in access to specialty care. For instance, specialists who visited the local hospital on a regular basis become unavailable to residents in the area after the hospital closes, or residents lose their access point for referrals to subspecialists. In addition, once hospitals close other resources dwindle, such as home health, pharmacy, hospice, and emergency medical services care, thus leading to hospital deserts and a dramatic decrease in access to and continuity of care for residents.

With the number of hospital deserts increasing, residents are forced to seek care elsewhere, if at all. In a 2018 Government Accountability Office report, elderly and low-income populations were more likely to be negatively impacted by rural hospital closures, and these populations were also found to be more likely to delay or forgo care after a hospital closure if the patient had to travel longer distances.

Finally, it is important to note that not all rural hospital closures lead to a complete depletion in access to care for residents. There has been some success with transitions to community-based primary care following a hospital closure. In this scenario local residents still have access to primary care services, but not necessarily critical services, such as those necessary for cardiac arrest or stroke. Currently there is no systematic approach to determine which services are critical to provide locally or virtually, and not every hospital closing can be smoothly transitioned into a primary care facility to address residents' healthcare needs.

Background

The Council discussed the growing trend of hospital closures in rural and medically underserved areas on access to and continuity of care as it relates to safe and effective medication use, primary care, and population health. The Council recommended the Section of Inpatient Care Practitioners (SICP) Section Advisory Group on Small and Rural Hospitals review the proposed



policy draft clauses to help influence the content. As part of the ASHP grassroots advocacy agenda, the Council stressed the need for ASHP to work with its constituents to influence state legislators, payers, and boards of pharmacy for supporting safe, innovative, and scalable approaches to preserving care in rural and medically underserved areas. This includes adoption and use of telepharmacy, subsidizing infrastructure needs (e.g., for USP Chapter 797 compliance), and a sustainable payment model. The Council also discussed the need for effective recruitment and retention strategies to offset the paucity of pharmacist and pharmacy technician skill sets in underserved areas, even those areas with ready access to telehealth. This includes, but is not limited to, advocacy efforts in support of loan forgiveness and incentive programs for the pharmacy workforce to practice in underserved areas. Given the variety of topics in the proposed policy recommendation, the Council recommended that SICP, the Section of Pharmacy Practice Leaders, and/or the Section of Ambulatory Care Practitioners develop survival tools to help inform strategies to assist the underserved on the fringes of a large health system. Consideration should be given to how to build facility and digital infrastructure, identifying and supporting practice-based needs, fostering the recruitment and retention of pharmacy staff to bridge gaps in care, and staff development of a multifaceted pharmacist generalist to support these struggling practice settings. Finally, the Council also recommended SICP explore any publication, networking, and/or education needs to highlight best practices to preserve patient access to pharmacy services when a rural or medically underserved area grapples with closures.

3. Multistate Pharmacist Licensure

- To advocate for multistate pharmacist licensure to expand the mobility of pharmacists
- and their ability to practice remotely.

Rationale

Rapid changes in technology have increasingly allowed healthcare to be delivered at a distance, and the growth of health systems and the consolidation and closing of hospitals in rural areas have created a demand for practitioner mobility across state lines. The century-old state-by-state licensure model of pharmacy has not kept pace with these changes, creating barriers to care. The nursing profession has addressed this challenge by creating the enhanced Nurse Licensure Compact (NLC). Under the NLC, registered nurses and licensed practical/vocational nurses who meet uniform standards are granted one multistate license that provides the privilege to practice in their home state and any other NLC state. This licensing model protects the interests of the state in ensuring the qualifications of its healthcare providers while fostering provider mobility and distance healthcare, increasing access to care. This licensing model has demonstrated its value by growing to include 25 states over 20 years. In addition, the NLC reduces the cost and administrative burden of licensure to both healthcare organizations and providers.



Background

As the Council discussed the growing trend of hospital closures in rural and medically underserved areas, it concluded that multistate licensure could help address this challenge by encouraging telepharmacy and pharmacists' ability to practice in different states. The Board felt that the issue of multistate pharmacist licensure was sufficiently important and distinct that it merited a standalone policy.

4. Continuity of Care in Pharmacy Payer Networks

- To oppose provider access criteria that impose requirements or qualifications on
- 2 participation in pharmacy payer networks that interfere with patient continuity of care
- 3 or patient site-of-care options.

Rationale

As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacies (e.g., specialty, outpatient infusion) and pharmacists working in those settings increasingly find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate), but when creating provider networks, payers should also consider the potential impacts on a patient's care and choice. Patients generally choose pharmacies that are most convenient for them. When providers or pharmacies are locked out of a payer network, patients may face barriers (e.g., physical access) to therapy, which can delay or otherwise frustrate treatment. Pharmacies within health systems have an advantage when it comes to electronic health record (EHR) integration, proximity and relationship to providers, and in some cases onsite clinical pharmacy specialists. This clinically superior environment, coupled with health systems' ability to measure and meet outcome-based metrics, allows them to easily show their performance against other pharmacies. Therefore, giving payer network access to integrated health-system pharmacies could improve care coordination and quality-based care, and reduce overall cost.

Background

The Council reviewed ASHP policy on pharmacist and pharmacy access to provider networks and recognized a need to address the potential impact of provider access criteria on patient continuity of care, and the Board agreed that a standalone policy was needed to address this gap. The Council also recommended an ASHP partnership with other nonpharmacy associations for leverage and a broader advocacy message related to integrated end-to-end, patient-centered care, not just for billing but also for managing the patient experience and outcomes, including deprescribing opportunities. This approach is centered on keeping care within a system, without financial penalty or denied reimbursement, if that health system is not the payer-preferred site of care. The Council also recommended that ASHP provide education for members on how to navigate and succeed in a payer-directed world and the impact of risk-



sharing arrangements on transparency. Finally, ASHP should consider a survey of ASHP members to determine the scope of impact related to exclusionary pharmacy payer network requirements to help further inform the advocacy message.

5. Health-System Use of Medications Supplied to Patients

- To encourage hospitals and health systems not to permit administration of medications
- brought to the hospital or clinic by the patient, caregiver, or specialty pharmacy when
- storage conditions or the source cannot be verified, unless it is determined that the risk
- of not using such a medication exceeds the risk of using it; further,
- 5 To support care models in which medications are prepared for patient administration by
- the pharmacy and are obtained from a licensed, verified source; further,
- 7 To advocate adequate reimbursement for preparation, order review, and other costs
- 8 associated with the safe provision and administration of medications.

Note: This policy would supersede ASHP policy 0806.

Rationale

Medications brought into a hospital or health system without an institution's direct oversight raise questions about a product's proper storage and pedigree. These include patient home medications, including specialty pharmaceuticals (i.e., brown-bagging) brought in by the patient or caregiver, and specialty pharmaceuticals shipped directly from a specialty pharmacy directly to the location where they are being administered (i.e., white-bagging). The hospital or health system should have policies and procedures in place and make a reasonable attempt to verify the medication pedigree and product integrity to ensure safe and appropriate administration of medications. Health and pharmacy benefit management models should ensure fair reimbursement and payment for medication preparation and administration and in the provision of direct patient care services for medications supplied to patients from a supplier outside of a hospital or health system.

Background

The Council reviewed ASHP policy 0806, Health-System Use of Medications and Administration Devices Supplied Directly to Patients, as part of sunset review and voted to recommend splitting it into two policies, one focused on medications brought into a hospital or health system without the institution's direct oversight (this recommendation) and one focused on safe and appropriate use of administration devices brought into facilities by patients (see Voted to Recommend 10 below). The Council voted to recommend amending ASHP policy 0806 as follows (underscore indicates new text; strikethrough indicates deletions):



To encourage hospitals and health systems not to permit administration of medications brought to the hospital or clinic by the patient, or caregiver, or specialty pharmacy when storage conditions or the source cannot be verified, unless it is determined that the risk of not using such a medication exceeds the risk of using it; further,

To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients) unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices.

6. Health-System Use of Administration Devices Supplied Directly to Patients

- To encourage hospitals and health systems not to permit the use of medication
- administration devices with which the staff is unfamiliar (e.g., devices brought in by
- patients), unless it is determined that the risk of not using such a device exceeds the risk
- 4 of using it; further,
- 5 To advocate adequate reimbursement for preparation, order review, and other costs
- 6 associated with the safe provision and administration of medications and use of related
- 7 devices; further,
- 8 To encourage hospitals and health systems to train staff on the handling and use of
- 9 medication administration devices brought in by patients; further,
- To advocate that hospitals and health systems ensure that pharmacists participate in
- the identification of medication administration devices brought in by patients and
- communicate those findings to the interprofessional care team.

Note: This policy would supersede ASHP policy 0806.

Rationale

The potential exists for serious patient safety and liability issues for healthcare staff when the use of patients' own infusion devices is allowed. Devices unfamiliar to staff are particularly risky and may result in patient harm. There are, however, occasions when the benefits of using



patients' own devices may outweigh the risks. Organizational policies and procedures should exist for handling such situations, complemented by expedient methods to gain familiarity and competency demonstration with a device. A pharmacist should be available to verify the medication and the associated device and use a technique (e.g., SBAR, team huddle) for communicating critical information to the interprofessional care team.

Background

The Council reviewed ASHP policy 0806, Health-System Use of Medications and Administration Devices Supplied Directly to Patients, as part of sunset review and voted to recommend splitting it into two policies, one focused on medications brought into a hospital or health system without the institution's direct oversight (see Voted to Recommend 9 above) and one focused on safe and appropriate use of administration devices brought into facilities by patients (this recommendation). The Council recommended amending two clauses from ASHP policy 0806 as follows (underscore indicates new text; first two clauses are from ASHP policy 0806):

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients), unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices; further,

To encourage hospitals and health systems to train staff on the handling and use of medication administration devices brought in by patients; further,

To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team.



7. Staffing for Safe and Effective Patient Care

- To encourage pharmacy managers to work in collaboration with physicians, nurses,
- health-system administrators, and others to outline key pharmacist services that are
- essential to safe and effective patient care; further,
- 4 To encourage pharmacy managers to be innovative in their approach and to factor into
- their thinking the potential benefits and risks of flexible staffing models, legal
- 6 requirements, accreditation standards, professional standards of practice, and the
- 7 resources and technology available in individual settings; further,
- 8 To support the following principles:
 - Sufficient qualified staff must exist to ensure safe and effective patient care;
 - During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
 - Within their own organizations, pharmacists should develop contingency
 plans to be implemented in the event of insufficient staff—actions that
 will preserve services that are the most essential to safe and effective
 patient care and will, as necessary, curtail other services; and
 - Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

Note: This policy would supersede ASHP policy 0201.

Rationale

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The advancement of the pharmacy profession over the past decade has prepared and positioned pharmacists to care for complex patients and adapt to the dynamic and rapidly progressive field of medicine. Throughout the years, an increased involvement of pharmacists in specialty areas such as transplant, critical care, oncology, and pain and palliative care has been observed. Therefore, it is imperative that such advancement is considered when developing staffing models, in order to ensure the pharmacy workforce is appropriately allocated for the provision of consistent, safe, and high-quality patient care.

The complexity of patient care will continue to increase, and with that, so will the expected responsibilities, opportunities, and skills of the pharmacy workforce. Consequently, pharmacists engaged in direct patient care are encouraged to pursue and maintain their training and credentialing in order to continue to enhance their competency, skills, and participation in

innovative practice. The expansion and dynamic nature of the pharmacy profession requires



new approaches to explore flexible staffing models to avoid a stagnant practice, encourage continual advancement, and accommodate the evolving priorities of the pharmacy workforce. The development and implementation of flexible staffing models can enable pharmacists to engage in further professional development and career advancement (e.g., training in areas of specialization, degree programs) and enjoy a more stable work-life integration experience. Recently, more attention has been drawn to burnout, resilience, and job satisfaction among the pharmacy workforce. Research has shown that pharmacists are reporting increased job stress over the previous years and that approximately 53% of pharmacists are reporting a high degree of burnout, which can consequently threaten patient safety. Therefore, there is an imperative to develop staffing models to meet staff members' changing priorities and for additional flexibility in the workplace. Implementation of flexible staffing models could improve performance and joy in the workplace. Pharmacy leaders should be committed to maintaining high-quality and consistent patient care services and to also promote models that balance patient care with staff priorities.

Various options to consider when exploring flexible staffing models are remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy technicians' roles to support pharmacist engagement in direct patient care activities. Some institutions have explored datadriven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services. Similarly, other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, patient acuity, collaborative staffing, and supplemental staffing model. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.

Background

The Council reviewed ASHP policy 0201, Staffing for Safe and Effective Patient Care, and voted to recommend amending it as follows (<u>underscore</u> indicates new text):

To encourage pharmacy managers to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care; further,

To encourage pharmacy managers to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,



To support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care;
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
- Within their own organizations, pharmacists should develop contingency plans
 to be implemented in the event of insufficient staff—actions that will preserve
 services that are the most essential to safe and effective patient care and will, as
 necessary, curtail other services; and
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

The Council recommended ASHP (possibly the New Practitioners Forum) survey members about the use of innovative staffing models to combat burnout and maintain well-being and resilience. Membership education on the survey results and identified best practice pearls should follow. The Council recommended ASHP update its Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel. Finally, ASHP should further support the study, publication, and promotion of such staffing models that provide flexibility for practitioners in the continuously evolving profession of pharmacy, without sacrificing consistent, safe, and high-quality patient care.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing <u>ASHP policies</u>, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs (1521)
- Pharmacist's Role in Population Health Management (1523)
- Pharmacy Staff Fatigue and Medication Errors (0504)
- Disposition of Illicit Substance (1522)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality



Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

The Council discussed the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive as part of sunset review. The Council determined the statement is in need of a contemporary update to include, but not be limited to, entrepreneurial, data science, supply chain, health benefit design, and the system vs. matrixed organization aspects that face today's pharmacy executive. The Council recommended the Section of Pharmacy Practice Leaders identify volunteers to review and update the statement. Members of the Council volunteered to work with the Section members to finalize the statement.

Application of USP Standards

The Council discussed recent guidance from the American Urological Association (AUA) and the American Society of Clinical Oncologists (ASCO) that would likely conflict with most hospital and pharmacy department interpretations of United States Pharmacopeia (USP) standards and determine the need for ASHP policy or action. Bacillus Calmette-Guerin (BCG) preparation has become an interesting topic, with the American Urological Association (AUA) issuing guidance to their members that is likely in conflict with most hospital and pharmacy department interpretations of USP chapters 795, 797, and 800. ASCO is also issuing information to their members that does not reflect best practice consistent with USP chapters 795, 797, and 800.

Of note, there have been seven appeals filed from various groups that could result in



further changes and/or postponement of the December 1, 2019, implementation date for all three USP chapters. Most appeals focused on beyond-use date provisions in both chapters 795 and 797. There was an appeal on the applicability of the chapters to veterinary practice, an appeal to the removal of language in current chapter 797 that allows the use of "new technologies and techniques," and an appeal to the reference to Controlled Environment Testing Association certification of engineering controls in chapter 797. There were also appeals to postpone the implementation date. Consequently, there may or may not be changes to the chapter. Even if there are no changes, there is a chance that the appeal process will force a delay in the December 1, 2019, implementation date.

The Council recommended that ASHP create educational resources that provide guidance on the topics, including case studies to define successful application of USP standards, presentations at professional medical meetings to bring awareness and understanding of the USP standards, and practical tips in layman's terms, specific to care setting, for other national medical associations regarding the proper handling and preparation of hazardous medications and compounded sterile and nonsterile products.

The Council agreed a more strongly worded policy to address the handling issues and patient safety concerns is needed. The Council suggested the Council on Pharmacy Practice (CPhP) consider more action based language for ASHP policies 0402 and 1711 to advocate for more ready-to-use formulations to minimize regulatory hurdles. Additionally, CPhP should explore any policy or guideline needs regarding the storage, handling, and transport considerations of USP chapter 800 for wholesalers and delivery drivers.

The Council mentioned ASHP should consider advocating for responsible oversight by an accrediting body to enforce USP standards in those practice settings outside accredited facilities (e.g., physician practice).

The Council also suggested ASHP support research on safe practice with or without application of USP standards to determine if there is a medication quality and safety difference.

Integration of Displaced Community Pharmacists into Hospitals and Health Systems

Dr. Hill introduced the topic. The Council discussed how the job outlook for community pharmacists and health-system pharmacists varies based on the recent U.S. Bureau of Labor Statistics pharmacist employment model for 2018 – 2028. Members noted the anticipated negative growth trend with community pharmacy settings through 2028.

The Council recognized that community pharmacists have extensive experience in providing patient care through medication education, medication preparation, and immunizations and can effectively bridge gaps in care through medication therapy management, troubleshooting insurance-related issues, and completing prior authorization processes. Members expressed these functions could translate to help to fill voids and allow displaced community pharmacists to serve as effective members of a hospital or health-system pharmacy team. The Council also stated opportunities to reposition community-based pharmacists within hospitals and health-systems in a declining community-pharmacy job market is a potential means to support expanding ambulatory care portfolios and to fill critical needs in medically underserved settings. The Council asked whether ASHP policies address the



increasing challenge for the profession and how it could benefit hospitals and health systems.

With respect to postgraduate training, the Council pointed out community-based pharmacy residency programs exist to help ensure pharmacists receive training to serve as leaders in the community setting; however, completion of these programs is not widespread. Although organizations will determine minimum qualifications for employment, it was noted that the ASHP Pharmacy Advancement Initiative advocates that all entry-level pharmacists have completed an ASHP-accredited residency to work in a hospital or health system. These qualifications and/or the level of effort (e.g., time, investment cost) required to train this displaced population may limit the ability of community pharmacists to find meaningful employment in hospital settings.

Council members highlighted the success of the ASHP professional certificate programs to enhance the professional development of pharmacists and provide them with unique skills to advance patient care and practice. Members see these programs as a way to support pharmacist continuing professional development, particularly for displaced community pharmacists seeking employment in a hospital or health system.

The Council's discussion resulted in the following recommendations:

- Consider possible Council on Public Policy amendment of ASHP policy position 0218,
 Pharmacist Recruitment and Retention, and/or the ASHP Guidelines on the Recruitment,
 Selection, and Retention of Pharmacy Personnel, to address support of community
 pharmacists who have been displaced due to loss of employment through opportunities
 for integration within hospitals and health systems.
- Investigate opportunities for ASHP to target certificate programs for community pharmacists, to assist hospitals and health systems with the on-boarding, competency development, and integration of this segment in to acute care roles.
- Encourage tool creation in partnership with other community-based pharmacy organizations.
- Partner with colleges/schools of pharmacy and ASHP state affiliates to encourage them to emphasize pursuit of other than community-pharmacy roles within the profession.
- Explore AJHP publication opportunities (e.g., an editorial) addressing this issue.
- Consider as a joint council topic during ASHP 2020 Policy Week.



COUNCIL ON PHARMACY PRACTICE POLICY RECOMMENDATIONS

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners. Within the Council's purview are (1) practitioner care for individual patients, (2) practitioner activities in public health, (3) pharmacy practice standards and quality, (4) professional ethics, (5) interprofessional and public relations, and (6) related matters.

Linda S. Tyler, Board Liaison

Council Members

Jennifer Burnette, Chair (Texas)
Andrew Stivers, Vice Chair (Georgia)
Jason Bergsbaken (Wisconsin)
Michael Dickens (Idaho)
Karl Gumpper (Massachusetts)
Amanda Hansen (Ohio)
Barbara Hintzen (Minnesota)
Molly Leber (Connecticut)
Karen McConnell (Colorado)
Alex Mersch, New Practitioner (Iowa)
Brittany Riley (West Virginia)
Jamielynn Sebaaly (North Carolina)
Cassandra Schmitt, Student (Virginia)
Anna Legreid Dopp, Secretary

1. Role of the Pharmacy Workforce in Violence Prevention

- To recognize that violence in the U.S. is a public health crisis; further,
- To affirm that the pharmacy workforce has important roles in a comprehensive public
- health and medical approach to violence prevention, including leadership roles in their
- 4 communities and workplaces; further,
- 5 To encourage members of the pharmacy workforce to seek out opportunities to engage
- in violence prevention efforts in their communities and workplaces; further,
- 7 To promote collaboration between the pharmacy workforce and community and
- 8 healthcare organizations in violence prevention efforts; further,
- 9 To foster education, training, and the development of resources to prepare the
- pharmacy workforce for their roles in violence prevention; further,
- To support research and dissemination of information on the effectiveness of
- pharmacy-focused violence-prevention strategies.



Rationale

The World Health Organization defines violence as "the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation." The Centers for Disease Control and Prevention (CDC) reports that in the U.S. 7 people die a violent death each hour -- 47,000 from suicide and 19,500 from homicide annually -- and a 2015 report found more than 2.5 million violence-related injuries annually. The CDC estimates that violence costs the U.S. \$9 billion annually in medical costs and lost work, and a separate estimate places the cost of violence as a whole to U.S. hospitals and health systems at \$2.7 billion dollars in 2016. The staggering human loss and soaring costs have led numerous organizations of healthcare and public health professionals to label violence a public health crisis and take action to address violence as a public health problem. One prominent example is the American Hospital Association Hospitals Against Violence Initiative, which provides examples and best practices to address its three central topics: workforce and workplace violence, combating human trafficking, and preventing youth violence.

ASHP believes that members of the pharmacy workforce have "a responsibility to participate in global, national, state, regional, and institutional efforts to promote public health" and that the pharmacy workforce has important roles in primary, secondary, and tertiary interventions to prevent violence. The CDC National Center for Injury Prevention and Control, Division of Violence Prevention states that the different forms of violence they identify—child abuse and neglect, youth violence, intimate partner violence, sexual violence, elder abuse, and suicidal behavior—are strongly connected and share common risk and protective factors. Interventions the pharmacy workforce could be involved in include but are not limited to

- improving access to mental health services, including treatment for substance use disorder;
- screening to identify victims of or individuals at risk of violence;
- providing trauma informed care;
- providing lethal means counseling;
- supporting hotlines and community support systems for people in crisis;
- providing or promoting Stop-the-Bleed bystander training; and
- participating in or promoting community- or hospital-based violence prevention organizations.

To fill these important roles, members of the pharmacy workforce will need appropriate education, training, and resources. Although some education, training, and resources are appropriate for different healthcare providers, ASHP is committed to the development of resources to prepare the pharmacy workforce for pharmacy-specific roles in violence prevention and to supporting research and dissemination of information on the effectiveness pharmacy-focused violence-prevention strategies. In addition, institutional and community leaders need to be aware of the pharmacy workforce's commitment to preventing violence. ASHP is committed to raising awareness with other stakeholders of the profession's commitment to collaborate to end the cycle of violence in their institutions and communities.



Background

The Council considered the topic of violence after participating in the Joint Meeting on Violence and Firearm-related Injury and Death. The consensus of the Council is that ASHP policy related to the prevention of violence is needed to create member and stakeholder awareness and stimulate resource development. This policy is intended to be different from ASHP policies related to violence in healthcare settings, thereby emphasizing the intention of the policy to be focused on violence as a public health issue. The intent of the policy is to affirm the pharmacy profession's role in addressing violence using public health and medical models. In doing so, pharmacy personnel can leverage the policy to seek inclusion in public health intervention programs in their communities and institutions.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing <u>ASHP policies</u>, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Support for Second Victims (1524)
- Role of Pharmacists in Safe Technology Implementation (1020)
- Pharmacist's Role in Urgent and Emergency Situations (1527)
- Health Care Quality Standards and Pharmacy Services (0502)
- Standardization of Doses (1525)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law



enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council developed proposed policy based on the discussion.

Role of the Pharmacist in Ensuring Safe Use of Outsourced Products

The Council discussed whether ASHP policy adequately addresses the patient safety considerations of outsourced medications obtained by pharmacy departments from facilities registered as human drug compounding outsourcing facilities under section 503B of the Federal, Food, Drug, and Cosmetic Act ("503B compounding facilities"). The Council voted to request that the Council on Public Policy investigate potential ASHP policy advocating for more publicly available information regarding the quality of compounded sterile preparations produced by 503B compounding facilities.

Pharmacists have a role in ensuring patient safety and understanding regarding the use of compounded sterile preparations (CSPs) that have been obtained from an outside entity. Examples of considerations for ensuring safe use of outsourced CSPs include but are not limited to product labeling and packaging variability; pharmacy department handling of outsourced products, especially those that are high-alert medications; nonpharmacy healthcare personnel awareness of safety risks; error and safety concern reporting; and patient education.

Pharmacies are mandated by state boards of pharmacy and pharmaceutical manufacturers are required by USP <7> to adhere to certain medication labeling expectations. However, 503B outsourcing facilities are immune from such requirements, creating inconsistencies and variability in labeling and packaging (e.g., differences in how medication strength is denoted, look-alike labeling and packaging, and barcode scanning incompatibility).

In addition, pharmacy departments face special handling considerations in the procurement, storage, distribution, administration, and disposal of outsourced products that extend throughout the hospital and health system. These considerations include informatics decisions related to and actions required for the handling of outsourced medications in the electronic health record and policies and procedures needed to reduce the risk of error or minimize the harm from high-risk medications.

The Council noted the difficulty in prospectively evaluating the quality of CSPs produced by 503B compounding facilities. Purchasers are responsible for the quality of CSPs they purchase and assume liability for their use, but the information available from FDA inspections (e.g., information provided in FDA Form 483) is woefully inadequate for this task. Important information is often redacted on the publicly available Form 483, and the FDA explicitly states that a Form 483 "is not an all-inclusive list of every possible deviation from law and regulation." Even if it were, a list of violations from one inspection would be insufficient to evaluate a 503B compounding facility's performance over time, given the small sample size and the age of the information. Although purchasers are often required by state law to inspect facilities from



which CSPs are purchased or do so as a best practice, the differences between the sterile compounding processes they are most familiar with (i.e., those used in 503A compounding facilities) and those of 503B compounding facilities make such inspections difficult. These challenges are so daunting that many pharmacies do not contract with 503B compounding facilities except in the most exceptional of circumstances, preferring to perform their own compounding or outsourcing to 503A facilities when possible. The Council suggested that information from FDA inspections or a standard survey of 503B compounding facilities could be used to construct a quality rating system, such as that proposed in ASHP policy position 1818, Federal Quality Rating Program for Pharmaceutical Manufacturers, or that an independent third-party accreditor could ensure a standard level of quality through inspections and accreditation.

The Council also discussed potential roles for ASHP in helping members address these challenges. The Council suggested that the ASHP Guidelines on Outsourcing Sterile Compounding Services could be updated to provide more information on how to inspect 503B compounding facilities, how purchasers can evaluate the quality of 503B compounding facility products, how to evaluate contractor performance, and how different components of health systems can share information when they have separate contracting processes. The Council was encouraged to hear that the newly form Section of Inpatient Care Providers Section Advisory Group on Compounding was investigating the possibility of revising the ASHP guidelines. The Council also suggested that the ASHP Foundation Contractor Assessment Tool could be updated and made available. The Council also wondered whether it would be possible to consolidate information from different sources on 503B compounding facilities into a shared resource.

Drug Shortages

The Council voted to request that the Council on Public Policy consider amending ASHP policy position 1905, Mitigating Drug Product Shortages, to include the concepts in ASHP policy position 0002, Drug Shortages.

The Council reviewed ASHP policy position 0002, Drug Shortages, as part of sunset review, and voted to request that the Council on Public Policy consider amending ASHP policy position 1905, Mitigating Drug Product Shortages, to advocate that pharmaceutical manufacturers, distributors, group purchasing organizations, and regulatory bodies, when making decisions that could create drug product shortages, strive to prevent those decisions from compromising the quality and safety of patient care. The Council concluded that the subject fit well within policy position 1905 and that ASHP and members would benefit from having one consolidated policy position on the topic of drug shortages. The Council tabled sunset review of policy position 0002 until the Council on Public Policy reviews the request.

FDA Labeling Requirement to Dispense in Original Packaging

The Council voted to request that the Council on Public Policy investigate potential ASHP policy advocating that the FDA require more information in prescribing information to explain why a drug product should be dispensed in its original packaging.

The Council discussed challenges with maintaining inventory of medications packaged in



one-size-fits-all containers. The experience is that this practice increases medication waste when the opened package yields leftover product. The Council is requesting that the Council on Public Policy consider the need to advocate with the FDA to limit this practice by the manufacturers.

ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance

The Council voted to revise the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance. The Council suggested that the statement be updated to use less stigmatizing language throughout and include the following topics in the revision: substance use in the elderly, medication-assisted treatment, prescription and nonprescription drugs of abuse, vaping, accessing prescription monitoring plans, and rehabilitation and recovery services (including for professionals). The Council also suggested incorporating and reinforcing all current ASHP policy positions related to substance use. Several volunteers from the Council were identified (Amanda Hansen, Jamielynn Sebaaly, Brittany Riley, and Cassie Schmidt).

ASHP Guidelines on the Pharmacist's Role in Immunization

The Council voted to revise the ASHP Guidelines on the Pharmacist's Role in Immunization. The Council noted the need to revise the Guidelines on the Pharmacist's Role in Immunization. Topics suggested for inclusion in the revision include: pharmacy department's role in improving patient access to vaccines in health-systems, contemporize reimbursement language, reference current increase in outbreaks, acknowledge the use of pharmacist extenders in administration of vaccines, addition of Vaccine for Children policy language, reference to state immunization registries and interoperability with health information systems, the use of standing protocols, and pharmacy personnel role in addressing vaccine hesitation counseling and vaccine misinformation. Several volunteers from the Council were identified (Jennifer Burnette, Karl Gumpper, Molly Leber, and Alex Mersch).

ASHP Policy Positions on Controlled Substances Diversion

The Council voted to request the Council on Pharmacy Management to consider consolidating ASHP policy positions 1614, Controlled Substance Diversion and Patient Access, and 1709, Controlled Substance Diversion Prevention, to provide easier access to ASHP policy on the topic.

In the course of reviewing ASHP policy position 0021, Medication Errors and Risk Management, the Council noted potential redundancy between ASHP policy positions 1614 and 1709.



House of Delegates

New Business Item: Racial and Discriminatory Inequities

Sponsor: Mollie Scott

State or Entity Represented: North Carolina Email Address: mollie_scott@unc.edu

Additional signers:
John Armitstead, Past President
Melanie Dodd, NM
Christopher Edwards, AZ
Lea Eiland, AL
Christi Jen, AZ
David Lacknauth, FL
Sarah Lake-Wallace, TX
Jeff Little, KS
Mary Parker, NC
Jennifer Robertson, TN
Kethen So, CA
Zach Weber, Section of Ambulatory Care
Practitioners Kit Wong, DC

Subject: Racial and Discriminatory Inequities

Motion:

To acknowledge that racism, discrimination, and inequities exist in healthcare and society as a whole; further,

To assert that racism, or any form of discrimination or injustice, has no positive value in society and cannot be tolerated; further,

To feverently commit to creating a more just and inclusive healthcare system and society as a whole.

Suggested Outcomes:

- Form a diverse, representative task force and convene a summit to study systemic racism with the goal of creating new resources and deliverables for members that contribute to breaking down the barriers that contribute to systemic racism in healthcare and society as a whole.
- Prioritize the development of workshops and symposia for national meetings (i.e., ASHP Clinical Midyear, ASHP Summer Meeting, ASHP Preceptors Conference, ASHP Leadership Conference, and student conferences) that educate members on implicit bias and systemic racism that seek to dismantle racism, prejudice and ethnic oppression, and support freedom and human dignity.
- Perform a comprehensive review of existing ASHP policies (i.e., Cultural Competence, Racial and Ethnic Disparities in Healthcare) to ensure that they are up-to-date and reflect ASHP's commitment to standing against racism of any kind.
- 4. Establish a Section Advisory Group on Inclusion, Diversity, and Racial Equity within the new Section of Pharmacy Educators to develop recommendations and best practices in pharmacy education that positively impact the next generation of pharmacists and technicians.
- 5. Request that each ASHP Section and Forum identify a plan for addressing racial, discriminatory inequities in healthcare within their charges and deliverables.
- Incorporate new standards for education about implicit bias and systemic racism into ASHP-accredited programs including residency programs and technician programs.
- 7. Engage the pharmacy workforce in listening meetings that seek to understand the impact of racism on the lives of African American patients and healthcare professionals and identify strategies to improve healthcare equity and create an inclusive pharmacy workforce.
- 8. Create an ASHP Connect community that promotes health equity and social justice and showcases blogs and stories of how systemic racism impacts patients and healthcare professionals as well as success stories from individuals and organizations who are striving to promote human dignity and dismantle racism.
- Establish new collaborations with organizations both inside and outside of pharmacy who have demonstrated commitment to decreasing health inequities (e.g., American Medical Association, American Public Health Association, HBCUs, and NAACP).
- 10. Create and implement an action plan for recruitment of under-represented minorities to the profession of pharmacy in order to ensure that the pharmacy workforce reflects our patient populations.

House of Delegates

New Business Item: ASHP Support of WHO

Sponsor:

Marianne Ivey

State or Entity Represented: Past President Email Address: Marianne.lvey@uc.edu

Additional signers:

Philip Schneider, Past President

Subject:

ASHP Support of the World Health Organization

Motion:

To encourage ASHP and its members to strongly support the mission work of the World Health Organization (WHO) in its role in public health preparedness, prevention, and control to improve the health and wellbeing of people globally; further,

To prioritize the revision of the ASHP Statement on the Role of Health-System Pharmacists in Public Health.

Background:

In an age of global travel between and among countries the efforts to prevent, control, treat and eradicate diseases and conditions that decrease health and well-being of all peoples are critical to all countries independent of factors such as income and education. Addressing new vectors of disease transmission and behavioral conditions related to lifestyles and environmental conditions continue to provide challenges that need to be addressed. Agencies such as WHO that provide evidence-based warnings, guidelines, education, research and advocacy and collect data to help countries prepare their public health infrastructure are critical in providing all peoples with the tools and resources needed to address critical health issues globally. The current ASHP Statement on the Role of Health-System Pharmacists in Public Health was published in 2008 and should be reviewed and updated.

Suggested Outcomes:

The ASHP HOD will approve this new business and emphasize the importance of the role of WHO through its statement on the role of pharmacists in public health.



ASHP: Leading Through Unprecedented Times 2020 Report of the President and the Chief Executive Officer



Kathleen S. Pawlicki MS, RPh, FASHP ASHP President



Paul W. Abramowitz PharmD, ScD (Hon), FASHP ASHP CEO

To our esteemed colleagues and ASHP members, the past 6 months have been nothing short of extraordinary. As pharmacists, colleagues, friends, and family members, we all faced unanticipated challenges, and there is still much uncertainty ahead due to the coronavirus disease 2019 (COVID-19) pandemic.

We are disappointed that we were unable to gather with colleagues in Seattle, WA, for ASHP's Summer Meetings and Exhibition and the annual meeting of the House of Delegates. Without this traditional in-person gathering, we called on ASHP's creativity and ingenuity to bring together delegates, conduct key policy work, and find new ways to deliver elements of ASHP's world-class educational programming. We also acknowledge what we all lost: opportunities to network with our peers, to celebrate the annual Harvey A.K. Whitney Lecture Award winner, to usher in new leaders for ASHP's sections, forums and Board of Directors, and to witness the inaugural address of ASHP's new president, Thomas J. Johnson, PharmD, MBA, BCCCP, BCPS, FASHP, FCCM.

Traditionally, ASHP's chief executive officer and president deliver individual addresses to the House of Delegates in June. We work for months on these remarks, hoping that each speech will convey important and inspiring insights about ASHP and its members. But 2020 has been anything but traditional. And in the wake of COVID-

19's incursion on everyone's lives, it felt right for us to join together in a single address to share our thoughts, express our tremendous gratitude to you, and convey our hopes for a bright and prosperous path ahead.

The year 2020 will forever mark a period in ASHP history when pharmacy—and all of healthcare—came together under extraordinary circumstances to help patients and support those serving on the front lines of the pandemic. During this unprecedented time, ASHP embraced the "never settle" mantra of President Kathy Pawlicki's 2019 inaugural address by accelerating efforts to support members, working with local, state, and federal partners, and leading the profession through an unpredictable and often overwhelming public health crisis.

There is no other organization in the world like ASHP, with its remarkable 78-year history on the forefront of improving medication use and enhancing patient safety. ASHP's strength, relevance, and commitment to challenging the status quo have shined during the COVID-19 response, as we all met new challenges in a dynamic environment and proved that the pharmacy profession has never been stronger than it is today.

COVID-19 response

When the time comes to reflect on the effect of COVID-19 on the healthcare community and the profession of pharmacy, ASHP will be remembered for responding swiftly and decisively to ensure that pharmacists—and all healthcare professionals—had the critical tools and information they needed to care for COVID-19 patients.

In early March, ASHP launched a COVID-19 Resource Center that became a widely used hub within the healthcare community, offering regularly updated tools and guidance, news and podcasts, and policy and advocacy resources. Content that would have previously been restricted to members was made available to all healthcare professionals and anyone who needed access. In doing so, ASHP effectively increased the reach of these vital resources by more than 50%, underscoring the heavy use and effectiveness of the content.



Drug information. Facing a lethal, rapidly spreading virus with no known treatments remains a frightening prospect. ASHP members worked tirelessly on the front lines with physicians and other interprofessional colleagues to identify medications that help patients combat the disease. Theories and assumptions about many different drugs were in play within the healthcare community and in the public at large, resulting in real concerns about drug hoarding, supply chain issues, shortages, and adverse outcomes.

To assist in monitoring the rapid and dynamic flow of information about possible treatments, ASHP leveraged our comprehensive drug information expertise to develop the *ASHP Assessment of Evidence for COVID-19 Treatments*. The evidence-based table is updated regularly to provide clinical guidance on emerging therapeutic approaches to COVID-19. One of ASHP's most valuable COVID-19 resources, the table was downloaded more than 20,000 times between mid-March and the end of May.

In addition, ASHP published its *Recommendations for Stewardship of Off-Label Treatments for COVID-19*. The document, which was downloaded nearly 6,000 times during the spring months, is a general guide for prescribers, pharmacists, and patients about the appropriate use of experimental treatments. The recommendations address concerns about hoarding and inappropriate prescribing to help mitigate potential shortages of critical medications.

Understanding that comprehensive, accurate drug information is perhaps the most important tool for pharmacists during COVID-19 response, ASHP opened access to 2 of our most in-depth

resources, AHFS Drug Information and the Interactive Handbook on Injectable Drugs. This action ensured that all healthcare professionals could quickly access critical details on potential treatments. More than 26,000 new users took advantage of these important resources between March and June, equating to more than \$6 million in value for the healthcare community.

Clinical resources. ASHP's guiding philosophy in the advent of the COVID-19 pandemic was to give all healthcare professionals every possible advantage to optimize patient outcomes. In that spirit, ASHP took the unprecedented step to make our Critical Care Pharmacy Specialty Review Course, Practice Exam, and Core Therapeutic Modules package available for free for a limited time. More than 57,000 individuals enrolled to use these comprehensive resources. ASHP also gave healthcare professionals free access to pharmacy competency assessments related to emergency preparedness and infection prevention.

In total, ASHP made more than \$40 million in educational resources available free of charge to ensure that all healthcare professionals had access to vital information, tools, and resources to combat COVID-19.



Real-time information and connections. Timely information sharing and first-person perspectives have been critical tools in the fight against COVID-19. ASHP led efforts to connect members and other practitioners with stories and case studies from peers who were on the frontlines in epicenters like New York and New Jersey. ASHP ramped up production of its popular @ASHPOfficial Podcast, produced live webinars to highlight case studies and best practices from institutions around the country, and hosted Twitter chats to connect peers in real time.

In addition, ASHP created an open COVID-19 Connect Community for members and colleagues to share information and engage with peers everywhere. More than 55,000 professionals engaged in the community, generating more than 1,200 discussion topics. The community enabled ASHP to share weekly pulse surveys on issues pharmacists were managing in the field. Insights gleaned from these surveys and the COVID-19 Connect Community helped ASHP create needed and timely resources.

ASHP also developed and launched CareerPharm RapidConnect. The service helps health systems, hospitals, and other healthcare organizations locate pharmacists and pharmacy technicians to fill COVID-19–related needs, including remote medication order review and verification and clinical pharmacy specialist services. CareerPharm RapidConnect, like other pandemic-response resources from ASHP, was offered free of charge to all healthcare professionals.

Policy and advocacy actions. The onset of COVID-19 created a significant imperative for

enhanced advocacy to ensure patient access to needed therapies and to support expanded roles for frontline pharmacists. ASHP was active at the local, state and federal levels, engaging regularly with policymakers, regulators, and key collaborators to support you and your interprofessional colleagues.

One of the pandemic's most significant challenges was the immediate effects on the supply chain. Patient care providers in early epicenter cities like Seattle and New York faced sudden shortfalls in supplies of personal protective equipment, respirators, and vital medications. ASHP worked tirelessly to spur federal agencies, including the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA), to remove administrative barriers within the drug supply chain that were impeding access to critical medications. And when remdesivir was granted Emergency Use Authorization by the FDA, ASHP was there to encourage transparency within the supply chain to help ensure adequate supply was directed to facilities in greatest need.

Due to ASHP's direct advocacy efforts, FDA clarified compounding guidance by removing the 1-mile radius requirement for hospital-compounded medications. FDA also relaxed requirements on 503A and 503B outsourcing pharmacies for hospital use of compounded medications and eased rules on the combining and repackaging of propofol.

DEA, in direct response to a letter cosigned by ASHP, the American Medical Association, the American Society of Clinical Oncologists, and the American Society of Anesthesiologists, increased annual production quota allocations for Schedule II controlled substances—medications that are essential for mechanically ventilated patients.

ASHP's efforts yielded further action from DEA when the agency relaxed limits on the distribution of controlled substances between practitioners, allowed distributors to ship controlled substances directly to satellite hospitals or clinics, and allowed for greater flexibility in opioid treatment programs.

ASHP also focused on efforts to increase pharmacists' scope of practice to aid in the COVID-19 response. In April, Department of Health and Human Services Secretary Alex Azar authorized licensed pharmacists to order and administer COVID-19 tests. The Centers for Medicare and Medicaid Services also issued rules allowing pharmacists to perform these tests. Many states expanded the role of pharmacists as part of state-of-emergency declarations. These orders were significant steps to provide needed assistance during the pandemic, and ASHP continues to push for expanded recognition of pharmacists by payers, including Medicare. ASHP also worked closely with its state affiliates and national organizations to push for pharmacist reimbursement during the pandemic.

One of ASHP's most important charges is to advocate on your behalf so that your voices are heard on issues that affect your practice and profession. ASHP is proud of the gains made to improve the odds against this frightening pandemic, but much work remains. ASHP will continue to harness its powerful

grassroots network on Capitol Hill and in statehouses across the country to help you fully leverage your expertise and training on behalf of your patients.

ASHP: innovator, influencer, and convener

It's hard to look back over the first half of 2020 and remember a time when we were not in the thick of the pandemic response. Nevertheless, ASHP staff and volunteers have been working diligently on many other critical initiatives to keep you on the forefront of medication safety and patient care and move the profession forward.

ASHP recently enriched its expertise and thought leadership with key staff additions that enhance the organization's ability to produce cutting-edge, world-class content. In December 2019, ASHP welcomed Past President Paul W. Bush, PharmD, MBA, BCPS, FASHP, as vice president of global resource development and consulting. The following month, Mary Ann Kliethermes, PharmD, joined ASHP as director of medication safety and quality. The addition of these highly



Paul W. Bush PharmD, MBA, FASHP



Mary Ann Kliethermes PharmD

respected and knowledgeable professionals to ASHP's already exceptional staff speaks to the organization's ongoing commitment to develop and deliver unparalleled resources that enhance medication use and patient outcomes on a global scale.

ASHP has long been a leader in the effort to identify enduring solutions to our nation's ongoing opioid crisis. In October 2019, we convened an interdisciplinary Opioid Task Force to identify actionable recommendations, built on existing national calls to action, and to provide a synergistic roadmap to address the epidemic while ensuring safe and effective pain management. Task Force members examined consensus findings and evidence-based best practices with the goal of providing fresh perspectives on how the unique skills and contributions of pharmacists can be leveraged to help solve this national problem.

The recommendations reflect the breadth, depth, direct experiences, and expertise of Task Force members. The team is uniquely qualified to identify solutions that address the opioid epidemic through better access to medication-assisted treatment and the development of stewardship programs and opioid-related community resources.

The final report of the ASHP Opioid Task Force unveils 69 recommendations spread among 9 domains. The report was approved by ASHP's Board of Directors in early April and has been submitted for publication in AJHP. The document will be widely disseminated across ASHP's communications channels and shared with colleagues, partners, and stakeholders with a goal of advancing the Task Force's recommendations.

Early this year, ASHP announced that it would convene a highly anticipated Summit on Safe, Effective, and Accessible High-Quality Medicines as a Matter of National Security. The live summit was scheduled to take place in March but was postponed due to the pandemic. We are very pleased that the event will take place virtually over the course of 5 days this summer. The summit is co-convened by ASHP, the American Hospital Association, the American Medical Association, and the United States Pharmacopeia. The agenda includes a topic made even more urgent in the wake of COVID-19: U.S. pharmaceutical supply chain resilience. Summit attendees will discuss the diversity of domestic and international ingredient and component sources needed to ensure a consistently safe, effective, and accessible supply of quality medicines, devices, and related supplies. The participants, who represent clinician groups, industry, supply chain entities, and government agencies, bring unique and diverse perspectives on the subject matter.

The summit findings will inform recommendations to improve public-sector and private-sector oversight of foreign drug manufacturing and support clinical decision making and communications with patients and others involved in healthcare delivery. The conveners fully recognize the heightened awareness around these issues, given the current COVID-19 public health crisis, and look forward to sharing the outcomes of the summit with members and key stakeholders.

ASHP's annual Commission on Goals was held in early March, just before local and national social distancing policies took hold. This interdisciplinary group of thought leaders reviews healthcare trends and provides guidance on potential strategic areas of focus for ASHP. This year, the commission was charged with identifying strategies to prepare the healthcare workforce to optimize patient-centered care and medicine in a future where ever-evolving technologies and disruptive innovations will be the norm.

The gathering featured robust, forward-thinking discussions about ensuring a highly competent and skilled healthcare professional workforce that will adapt and embrace innovation and emerging technologies to advance patient care. Commission members also examined the roles that healthcare professions, colleges, associations, government, and accrediting bodies play in reimaging the workforce for the digital future. Additional discussions centered on how healthcare industry and associations can help ensure the development of safe and effective new technologies and how data and evidence will propel technological advances. Proceedings of the commission's meeting will be published online ahead of print in a forthcoming issue of *AJHP*.

In response to a growing need to support and connect pharmacy executives, ASHP in March announced the creation of the Pharmacy Executive Leadership AllianceTM (PELATM). PELATM is a new engagement opportunity for chief pharmacy officers and pharmacy executive leaders at multihospital systems who face distinct challenges working within highly complex, vertically and horizontally integrated networks. To oversee this important endeavor, ASHP was pleased to promote

ASHP: Leading Through Unprecedented Times

long-time staff member David Chen, BSPharm, MBA, to the position of assistant vice president, pharmacy leadership and planning.

PELA participants will engage pharmacy executives in peer-to-peer knowledge transfer and the exploration of market trends and innovations to meet multifaceted operational and clinical needs. The timing of PELA allowed for the rapid development of facilitated discussions around COVID-



19 business recovery. A series of virtual roundtables proved valuable for sharing information on critical business effects of the pandemic. Participants discussed the need to plan for new operating policies and procedures, organizational plans for increasing revenue and patient volumes, how to leverage telehealth, and the management of COVID-19–related pharmacy expenses.

Findings from these roundtable discussions, as well as information and key learnings from other PELA initiatives, will support ASHP's members as they advance pharmacy practice, safe medication use, and improved patient outcomes.

ASHP derives its innovative spirit from its members, who demonstrate time and time again that settling for the status quo is never good enough. ASHP, at 55,000 members strong and growing, represents pharmacists, student pharmacists, and pharmacy technicians who are at the top of their game as they strive to achieve the very best in service to their colleagues and patients.

ASHP prides itself on representing members' professional and practice needs and anticipating how those needs will evolve across a broad range of practice settings. To this end, the ASHP Board of Directors recently approved a new membership section, the Section of Pharmacy Educators to further ASHP's commitment to preparing the pharmacy workforce. The section will be a home for individuals involved in educating, training, and mentoring student pharmacists, pharmacy residents, and pharmacy technicians across all learning and practice settings. Members of this new section will help crystalize ASHP's strategic focus on elevating competencies, skills, and credentials across the pharmacy workforce and help to maximize pharmacists' vital roles on interprofessional patient care teams.

In addition to providing new support for pharmacy for educators, ASHP continues its commitment to the training of pharmacy residents—the future leaders of our profession. During the 2020 ASHP Resident Matching Program, conducted in 2 phases this spring, 5,269 individuals matched with 2,551 pharmacy residency programs, continuing an era of unprecedented growth. Residency positions have increased by 46% over the past 5 years. ASHP and its Commission on Credentialing

proactively increased the flexibility of residency accreditation standards to address disruptions caused by the COVID-19 response, demonstrating continued commitment to residents and training programs.

Conclusion

As we write these words in anticipation of our virtual meeting of the House of Delegates in June, there will no doubt be new developments related to COVID-19 and its effects on patients and providers across the country. As our nation slowly starts to regroup and seek a return to some semblance of normalcy, those who have been working on the front lines of patient care understand that the virus remains a threat, and our perception of "normal" will likely never be the same.

It is our hope that as we reflect on the year 2020, it is defined not by adversity, but by our collective response to it. Throughout this great public health crisis, we have all witnessed tremendous displays of selflessness, compassion, and generosity from our colleagues, friends and family. We have all experienced the great power of collaboration and the uncompromising determination of a healthcare community dedicated to our patients' care and wellbeing against difficult odds.



Photo Courtesy of Massachusetts General Hospital

As we seek our path forward, it is that spirit of resilience and fortitude that will inspire and guide us. The

lessons we have learned will lead us into a future that remains bright with promise for our profession and members. On behalf of ASHP, we look forward to continuing to support you with unparalleled networking opportunities, world-class educational programming, and best-in-class clinical resources to empower and inform your career and practice today and for many years to come.

We are beyond grateful for the continued support you have shown ASHP and for your unwavering commitment to the profession of pharmacy and the care of your patients.

Thank you.

2020 Report of the ASHP Treasurer

Christene M. Jolowsky

Each year, the Treasurer has the responsibility to report to the membership on ASHP's financial condition. ASHP's fiscal year is from June 1 through May 31, coinciding with our policy development process and timetable. This report describes ASHP's actual financial performance for fiscal year (FY) 2019, projected financial performance for FY2020, and an FY2021 budget status update.

Fiscal Year 2019 Ending May 31, 2019—Actual

ASHP's FY2019 financial audit ending May 31, 2019, was performed by the independent audit firm of Tate & Tryon, which merged with RSM US LLP in January 2020. The audit resulted in ASHP receiving the best opinion available, an unmodified opinion.

ASHP's core operations¹ had another successful year. Core gross revenue grew to \$54.0 million or by 7.3% over FY2018 (Figure 1), primarily due to strong membership growth, the continued success of the Midyear Clinical Meeting, and growth in residency accreditation services and certification programs. Membership grew to nearly 49,500 as of December 31, 2018, which represents a 10% increase from the prior year. Core net income was \$971,000. Program development expenses, capital budget, and investment gain/(loss)² had net expenses of \$692,000, and ASHP's pension plan realized a gain of nearly \$1.1 million. In total, FY2019 resulted in a positive \$1.37 million net change in ASHP's reserves/net assets. Finally, the building fund³ had a deficit of \$3.15 million, primarily due to lower-than-budgeted investment returns. The building fund remains on track to continue supporting ASHP's office space expenses and reach its long-term financial target.

ASHP's reserves/net assets at May 31, 2019, represented 81%⁴ of total FY2019 expense. This is within our long-term financial policy of maintaining reserves/net assets within the Board of Directors approved guidelines of 50% minimum, 70% target, and 90% maximum.

ASHP's total net assets at the end of FY2019 were nearly \$129 million (Figure 2) and our year-end balance sheet remains strong, with an asset-to-liability ratio of 4.99:1.

¹Represents the revenue and expense associated with the operations of ongoing ASHP programs, products, and services, as well as infrastructure and ASHP Foundation support.

²Includes investments in ASHP's program development and capital budget, building sale reserve funds, reserves/net assets spending, and investment gains/(losses). The Board of Directors approves spending during ASHP's annual budget development process. Expenditures are typically (1) associated with new, enhanced, and expanded programs; (2) associated with time-limited programs; (3) capital asset purchases; or (4) supplemental operating expenses. These expenditures are primarily funded by investment income from reserves/net assets and the building sale reserve funds.

³Created to hold the net gain from the sale of ASHP's previous headquarters building. The long-term investment earnings are used to pay for lease and other occupancy-related expenses associated with ASHP's current headquarters office.

⁴The building fund is excluded from the reserves/net assets calculation due to its designated use.

ASHP's former subsidiary, the 7272 Wisconsin Building Corporation, which owned ASHP's previous headquarters building in Bethesda, Maryland, was dissolved on May 29, 2019.

Fiscal Year 2020 Ending May 31, 2020—Projected

Fiscal year 2020 core operations is shaping up to be another solid year, with projected revenue of \$56.2 million. As of February 29, 2020, we anticipate that ASHP's FY2020 core operations net income will be one of its strongest ever, with \$3.1 million in core operations net income (Figure 1). However, due to the COVID-19 pandemic, the financial markets have been extremely volatile. Due to this volatility, we are currently forecasting no investment returns in our 2020 projection. As a result, because investment returns are used to support ASHP's non-core operations, we are projecting expenses of nearly \$1.7 million for net program development expenses, capital budget, and investments. Finally, also due to projecting no building fund investment returns, we are projecting expenses of \$4.5 million.

One of the key reasons ASHP's core operations is so strong in FY2020 is the growth of its membership. ASHP membership reached nearly 53,500 as of December 31, 2019, which is another membership record. We are proud to continue to provide high-quality benefits, programs, products, and services that attract an increasing number of members.

To support our members and the profession during the COVID-19 pandemic, ASHP has quickly developed a comprehensive, free COVID-19 Resource Center that includes tools and guidance, news and podcasts, policy and advocacy resources and materials, and access to the COVID-19 Connect Community. Examples of additional free resources being provided by ASHP include but are not limited to access to the Critical Care Pharmacy Specialty Review Course and Core Therapeutics Modules, access to AHFS Drug Information, and certain modules in the Pharmacy Competency Assessment Center.

Fiscal Year 2021 Ending May 31, 2021—Budget

I am pleased to report that, in this time of economic uncertainty related to the COVID-19 pandemic, ASHP is prepared, remains financially strong, and has the financial reserves to support its core operations, including membership services, and to continue to invest in ASHP's future.

ASHP's Board of Directors thoughtfully considered the potential financial ramifications of the COVID-19 pandemic on ASHP's FY2021 budget. This included cancelling the Summer Meetings and a decision not to increase membership dues rates during calendar year 2021. The Board of Directors focused on positioning ASHP for the future, including continued support our members and the profession with timely, valuable resources, products, and services during these extraordinary times, acknowledging that this decision will likely result in using some of ASHP's reserves.

Taking into account the cancellation of the Summer Meetings, not increasing membership dues rates during calendar year 2021, adjusting for additional potential revenue decreases, and significantly reducing expenses, the core operations budget is balanced, with \$54.1 million in revenue. Net program development expenses, capital budget, and investments gain/(loss) are budgeted to invest nearly \$2.3 million in important initiatives and capital items with no offset from investment gains, as we budgeted ASHP's investments to remain flat during

FY2021. Finally, our building fund is designed to pay for ASHP's headquarters office space. We have budgeted for the associated occupancy costs, but similar to ASHP's other investments, we have not included any investment returns to offset expenses. We are hopeful that our economy will quickly recover, but felt it prudent to plan for no investment returns at this time.

Investments to Support Our Members and the Profession

Due to our strong financial position, we are pleased to have the resources to invest in new initiatives to better serve our members and the profession. Examples of key investments in recent years include the following: COVID-19 Resource Center and associated free resources; Pharmacy Technician Forum; addition of a Section of Specialty Pharmacy Practitioners; enhancing ASHP's government relations activities; advocating for provider status; joining the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience and the Action Collaborative on Countering the U.S. Opioid Epidemic; supporting Board of Pharmaceutical Specialties petitions for sterile compounding, solid organ transplant, emergency medicine specialties, and pain and palliative care; enhancing pharmacy residency and technician accreditation management systems; developing certification resources for many new specialties; developing certificate programs; expansion of ASHP's podcast programming; and investing in ASHP's website, learning management system, and AJHP. We continue to actively look to the future and invest in programs, products, and services that support our members and advance the profession of pharmacy.

Conclusion

The Board of Directors, Chief Executive Officer, and staff remain committed to ASHP's mission, vision, strategic plan, and supporting our members and the profession of pharmacy. We are proud to be a growing organization with nearly 54,000 members and to be at the forefront of improving medication use and enhancing patient safety. ASHP's financial strength and diversity of revenue sources, even in challenging times, allows for continued investment in our future. ASHP is positioned for the long term to continue to advance the profession and support its membership during good and bad times.

Figure 1. ASHP Condensed Statement of Activities (in thousands)

	Actual	Actual	Projection*
	Fiscal Year Ended May 31, 2018	Fiscal Year Ended May 31, 2019	Fiscal Year Ended May 31, 2020
CORE OPERATIONS			
Gross Revenue	50,310	54,000	56,165
Total Expense	(48,831)	(53,029)	(53,048
CORE NET INCOME	1,479	971	3,117
NET PROGRAM DEVELOPMENT EXPENSES, CAPITAL			
BUDGET, AND INVESTMENTS GAIN/(LOSS)	497	(692)	(1,657
Pension Plan Adjustment	425	1,093	0
NET CHANGES IN RESERVES/NET ASSETS	2,401	1,372	1,460
BUILDING FUND	(521)	(3,158)	(4,525

^{*}Projection as of February 29, 2020.

Figure 2. ASHP Statement of Financial Position (in thousands)

	Actual as of May 31, 2018	Actual as of May 31, 2019
ASSETS		
Current assets	5,743	11,573
Fixed assets	9,606	8,090
Investments	145,982	141,081
Other assets	471	224
Total Assets	161,802	160,968
LIABILITIES		
Current liabilities	20,356	22,036
Long-term liabilities	10,920	10,192
Total Liabilities	31,276	32,228
RESERVES/NET ASSETS		
Total Net Assets	130,526	128,740
Total Liabilities and Net Assets	161,802	160,968



House of Delegates

Recommendations from the 2020 House of Delegates

The delegate[s] who introduced each Recommendation is [are] noted. Each Recommendation is forwarded to the appropriate body within ASHP for assessment and action as may be indicated.

1. Autoverification

On behalf of the Joint SICP Section Advisory Group for Medication Safety, and SOPIT Clinical Decision Support and Analytics Task Force for Autoverification; New Hampshire Delegation: Keith Foster, Kristine Willett, Elizabeth Wade

To recommend that ASHP develop a call to action for regulatory agencies to clarify the role of autoverification in electronic health records

Background: Autoverification occurs when a medication is entered and released, bypassing the pharmacist verification step, and is automatically verified in the EHR. In the 2019 ASHP survey of health-systems, 62.2% of health-systems use autoverification functionality, a significant increase since 2016. However, regulatory standards are lacking; MM 05.01.01. states: "A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital." Autoverification is not specifically mentioned, and with the prevalence of its use in EHR's, clear guidance is needed from regulatory agencies.

2. Amendment to CPM 1808 Patient Access to Pharmacist Care within Provider Networks

JoAnn Stubbings, Section of Specialty Pharmacy Practitioners

On behalf of the Section of Specialty Pharmacy Practitioners, I would like to recommend the Council consider the following amendment to 1808 Patient Access to Pharmacist Care within Provider Networks: To advocate that the criteria developed by the healthcare payer is transparent to and standardized across all network providers in order to ensure the same level of patient care within the network.

Background: This policy as written addresses the criteria for pharmacists or pharmacies to participate in healthcare networks. The proposed amendment addresses a practice among healthcare payers in which the payer's stated criteria are not standardized across all network participants, resulting in different levels of patient care within a network. For example, the criteria for a health system pharmacy to participate in a specialty or infusion contract may be different from the healthcare payer's criteria for

its own specialty or infusion pharmacy. Due to a lack of transparency and standardization across all network providers, the level of patient care may not be the same within the network.

3. Labor and Reimbursement Practices for Frontline Pharmacy Personnel During Unprecedented Times

Mindy Burnworth, Arizona; Christi Jen, Arizona; Christopher Edwards Arizona; Andrew Mays, Mississippi

To advocate that ASHP ensure that pharmacy personnel are included in federal legislation regulating labor and reimbursement practices for frontline essential workers with known exposure to serious disease for which adequate protection cannot be provided or during a natural disaster, public health emergency, pandemic, and unprecedented times.

Background: The current COVID19 pandemic prompted the consideration of hazard pay and labor/reimbursement practices for frontline essential workers with known exposure to serious disease for which adequate protection cannot be provided. Federal laws supporting such hazard benefits include US Department of Labor and Code of Federal Regulation. Several national pharmacy organizations including NCPA, APhA, and ASHP advocated for inclusion of pharmacists in the Heroes Act. Moving forward, pharmacy personnel should be included in similar legislation from the beginning.

4. Alternative and Virtual Residency Learning Experiences during Unprecedented Times Mindy Burnworth, Arizona; Christi Jen, Arizona; Christopher Edwards Arizona; Andrew Mays, Mississippi

To recognize that in-person, hands-on clinical experience provides the most meaningful learning opportunities in resident learners, further;

To encourage ASHP explore the impact of virtual or alternative learning experiences during residency training (PGY1, PGY2) during exceptional or unprecedented times, further;

To encourage that ASHP Residency Accreditation Standards address virtual or alternative learning experiences during exceptional or unprecedented times.

Background: The current COVID19 pandemic prompted the need for virtual or alternative pharmacy practice learning experiences (introductory and advanced) for student learners. These novel learning experiences mandated accelerated creation and rapid collaboration with ACPE, AACP, state boards of pharmacy, and colleges of pharmacy to ensure "reactive" approval. These valuable "lessons learned" about education during a pandemic prompted a reflection on resident learners and how



learning/teaching may require adaptation. ASHP is encouraged to explore the possibilities of having virtual or alternative learning experiences during residency training should the need arise. This proactive approach will ensure consistent learning and precepting during exceptional and unprecedented times and can be further highlighted in ASHP Residency Accreditation Standards.

5. Role of the Pharmacy Workforce in Pandemics

Mindy Burnworth, Arizona; Christi Jen, Arizona; Christopher Edwards Arizona; Andrew Mays, Mississippi

To recognize that pandemics in the U.S. are a public health crisis; further,

To affirm that the pharmacy workforce has important roles in a comprehensive public health and medical approach to pandemics, including leadership roles in their communities and workplaces; further,

To foster the continued expansion of education, training, and resources to prepare the pharmacy workforce for their roles during a pandemic; further,

To support research and dissemination of information on the effectiveness of pharmacy-focused pandemic-management strategies.

Background: While ASHP has Statements on the Role of Health-System Pharmacists in Emergency Preparedness and Role of Health-System Pharmacists in Public Health, the intent of these statements was to "stimulate dialogue" about the role that health-system pharmacists can play in providing care that improves public health in the United States. To modernize the intent of these statements and document the revolutionary progress that the pharmacy workforce demonstrated during the COVID19 pandemic (remdesevir & other evidence-based agents, screening), ASHP is encouraged to refine these statements and create a free-standing policy to better highlight the proven benefits and activities of the pharmacy workforce during a pandemic (evaluating the literature for evidence-based management during a pandemic). In addition, it is important that the pharmacy workforce be provided with the appropriate education, training, and resources (including personal protective equipment) to foster pharmacy's continued success in the management of pandemics, while preserving their health.

6. Dissemination of ASHP Political Action Committee Report during House Proceedings Mindy Burnworth, Arizona; Jeff Little, Kansas

To affirm that ASHP is committed to advocacy as a professional obligation; further,

To strongly encourage that ASHP disseminate the ASHP Political Action Committee (PAC) Report in its entirety as a line item during the annual House of Delegates proceedings.



Background: ASHP recently published a statement on Advocacy as a Professional Obligation. To elevate the role of ASHP in promoting advocacy, reporting of the ASHP Political Action Committee (PAC) Report [like the President's Report and Treasurer's Report] during the House of Delegates meetings is appropriate. Sharing of the PAC Report will also foster increased awareness of advocacy as a professional obligation. Dissemination of the PAC Report could be via various methods: oral or written report outlining PAC donations, PAC expenditures, and balance on hand.

7. ASHP Pharmacy Residency Verification Database

Florida delegation: Farima Fakheri Raof, Bill Kernan, Jeffrey Bush, Dave Lacknauth, Michael DeCoske, Gary Dalin

ASHP to develop a Pharmacy Residency Training Verification Database

Background: Currently there is no database or verification process to confirm if a pharmacist has successfully completed a residency training program. Having access to an online database which lists individual names, residency program/entity name, program completed and residency graduation date will be a helpful tool in pharmacy recruiting processes.

8. ASHP Residency Trained Credential

Florida delegation: Farima Fakheri Raof, Bill Kernan, Jeffrey Bush, Dave Lacknauth, Michael DeCoske, Gary Dalin

ASHP to explore the creation of a Residency Training Credential to be used by pharmacists who have successfully completed an accredited residency training program

Background: Completing a residency training has been highly encourage by ASHP and is now an important step in advancing pharmacist training. However, it is often observed that the members of multidisciplinary teams are not familiar with or aware of pharmacy residency trainings. Dedicating a formal credential will help bring awareness in regards to these advanced trainings similar to Pharm.D., BCPS, CPh and other credentials.

9. Primary Source of Raw Materials for Medication

Brian I. Kawahara, California

ASHP should recommend that the FDA and other government entities mandate manufacturers find and use more than one source of raw materials for medications especially those needed for emergent situation (e.g., those needed on crash carts, oncology medications, etc.)

Background: The recent Covid-19 crisis and other disasters have led to a shortage of several critical medications due to the dependence of obtaining raw materials from a



single source (e.g., China or India). This has led to delayed or change in therapy and increased the risk of medication errors. It has also been seen when contamination occurs in the raw product (e.g., metformin, ranitidine, etc.) leading to recalls of finished product from several manufacturers. Also, this has led to development of "gray" or "black" market suppliers increasing the likelihood of a counterfeit product being received. This situation cannot continue as it endangers the lives and well-being of patients.

10. Virtual Access to ASHP Midyear

New York Delegation; Liz Shlom, Karen Berger, Heide Christensen, Ruth Cassidy, Frank Sosnowski

We recommend that ASHP plan to provide virtual access to meetings and events at the ASHP Midyear 2020.

Background: Some hospitals (one of the NYS delegates works at such a hospital) have already stated that their staff are not permitted to attend conferences in 2020. Not knowing how the Fall will unfold in regards to a second wave of COVID-19, it is recommended that ASHP plan for at least some members not being able to attend in person.

11. Pharmacist Role in Global Health Threats

David Hager, Wisconsin

ASHP create policy in relation to the pharmacists role in Global Health Threats including pandemics.

Background: I am sure there will be many asking for this and wanted to make sure it was included.

12. Pharmacist Response to Global Warming

David Hager, Wisconsin

ASHP craft a policy on the impact global warming will have on public health, pharmaceutical use and global health as well as the pharmacists role mitigating global warming.

Background: Global health will change as the earth continues to warm. As a result so will pharmaceutical use (Journal of Toxicology and Environmental Health, Part B, 16:285–320, 2013). Policy on a pharmacists involvement would guide policy.

13. Opposition to Patent Protection by Transfer to Native American Populations David Hager, Wisconsin



To craft policy in opposition of pharmaceutical companies use of Native American's sovereign status under federal law made the patents immune from administrative review from the US patent office.

Background: Allergan attempted this in 2019. We should oppose this abuse of native populations.

14. Productivity Metrics

Molly Leber, Connecticut

Recommend that ASHP create a Task Force or develop a White Paper around safe staffing ratios, future guidance on the use of productivity metrics and value based care

Background: Recognizing that as for-profit organizations are expanding and other organizations are looking for cost savings, there is a need to create a minimum staffing ratio, similar to what nursing has. It is recommended that ASHP create a Task Force or develop a White Paper around safe staffing ratios and future guidance on the use of productivities metrics and value based care.

15. Virtual Regional Delegate Conferences

Washington, DC Metro delegation: Michelle Eby, Kit Wong

Beginning in 2021, we recommend that all Regional Delegate Conferences (RDCs) are held virtually.

Background: Virtual RDCs allow for increased attendance, reduced cost to ASHP, and reduced cost to members. They also allow members from distant states to network who would otherwise not have the opportunity to do so. If ASHP decides to hold RDCs virtually, you may consider changing the name as they will no longer be regional. Perhaps they can be called Virtual Delegate Conferences (VDCs).

16. Survey of Strategic Planning Performed by Health-System Pharmacies Andrew Donnelly, Illinois

Recommend that the extent, if any, of strategic planning in health-system pharmacies be assessed by ASHP via a standalone survey or in conjunction with a broader survey being performed by ASHP.

Background: A recent literature search that I performed on strategic planning in health-system pharmacies when getting ready to do strategic planning in my department resulted in very few articles on this topic, with the majority being quite dated. However, it was reported that hospital pharmacy departments that performed strategic planning resulted in administrators having a greater satisfaction with the department and that the department had a higher number and quality of clinical pharmacy programs. I think



the general membership of ASHP, especially those in management/leadership positions, would benefit from a well-designed survey assessing how departmental strategic planning is structured, the strategic priorities identified, and the mechanism used for implementation of the plan.

17. Hospital/Health-System and Insurer Partnership

Justin Konkol, Wisconsin

Encourage ASHP to engage with Insurers and Health-Systems around developing sustainable financial models for both interested parties to prevent segmented care from occurring (primary care in a non-affiliated clinic, infusion at a non-health-system infusion entity).

Background: Through vertical integration insurers continue to carve out care from hospitals and health-systems from providing patient care offerings which include but are not limited to infusion services, urgent care etc. The reason for this carve-out is routinely due to being able to provide care at a lower cost. Would be interested in some demonstration projects or partnership developments that can help maintain the patient continuity and care delivered AND meet both the insurer and hospital-health-system financial goals.

18. Development and Creation of Sustainable Telehealth Business Models Justin Konkol, Wisconsin

Recommend ASHP help members create and develop robust toolkits and business plans around implementing, sustaining, and growing telehealth services.

Background: With COVID-19, organizations such as my own have recommitted to providing 1/3 of their care virtually. Currently, except under emergency rules, many pharmacists providing telehealth services do not receive reimbursement for these services. With facility fee charging not applicable to virtual visits, our profession needs support to redefine the role of the pharmacist in telehealth.

19. Developing an Engaged Work-from-Home Pharmacy Workforce Justin Konkol, Wisconsin

I would encourage ASHP to help develop and create training, tools, and programming for pharmacy leaders around how to best manage, maintain, and engage pharmacy team members with team members working in multiple sites.

Background: Many organizations are moving to permanently keep workers at home, displaced by COVID, at home. There is already some information being shared on virtual burnout. We as leaders will require new tools, techniques, and support to attract new



talent, engage team members, and work through the new virtual barriers created to remain successful to care for our patients and execute on our organizational goals.

20. Investigational Drug Services Sustainable Business Model

Justin Konkol, Wisconsin

Would encourage ASHP to help develop toolkits, staffing metrics and other useful business tools to manage departments who manage investigational drug programs.

Background: The amount of work to manage investigational drug programs continue to skyrocket with complexity and numbers of studies continuing to expand. There is not universal metric to evaluate acuity or complexity of a study (Vizient has published some data) around this topic. Additional surveys, presentations, publications around the business operations of this complex environment are sparse at best.

21. Opposition to Laws and Regulations That Limit or Deny Access to Health Care and Health Care Information and Interferes with Provider/Patient Relations Brian I. Kawahara, California

That ASHP opposes the passage of federal, state, and local health care legislation and/or regulations that are designed use values or religious philosophies rather than scientifically based evidence to deny or interfere with the ability of a patient to access provider services and/or health care information to make a decisions about their health care, resulting in the denial, removal, or prohibition of their constitutional rights and freedoms, even though the individual is of legal age and sound mind.

Background: Several states have passed laws and create regulations that infringe upon a patient of sound mind and legal age, access to healthcare services and/or a decision between health care provider and patient for healthcare procedures based. These laws and regulation are based on values rather than scientifically based evidence. Since pharmacists are patient advocates, ASHP should protect basic rights to healthcare and provider-patient confidentiality. This recommendation is written broadly to cover not only current laws and regulations but future ones that infringe on these basic rights.

22. Best Practice for Managing a Strategic National Stockpile

Colorado Delegation: Michelle Then, Jennifer Davis, Karen McConnell

We recommend that ASHP work with state, federal, and industry partners to create a best practice for managing a strategic national stockpile of critical medications for hospitals as well as creating a plan for distribution of new drugs/vaccines to ensure adequate supply, transparency and prompt response in the event of pandemics and emergencies.

Background: We recommend that ASHP work with state, federal, and industry partners to create a best practice for managing a strategic national stockpile of critical



medications for hospitals as well as creating a plan for distribution of new drugs/vaccines to ensure adequate supply, transparency and prompt response in the event of pandemics and emergencies.

23. ASHP Response to Racial Injustice

Mollie Ashe Scott, Zachary Weber

New Business Item:

- 1. We recommend that ASHP develop a statement or policy that supports widespread education for pharmacists, residents, students, and technicians about implicit bias and systematic racism.
- 2. We recommend that a Section Advisory Group be established within the new Section of Education to support educational initiatives on inclusion, diversity, and racial inequity.

Suggested Outcome:

Creation of resources and deliverables for ASHP members that contribute to breaking down barriers that support systemic racism in healthcare.

24. ASHP Support of the World Health Organization

Marianne Ivey, Philip Schneider

New Business Item:

To encourage ASHP and its members to strongly support the mission work of the World Health Organization (WHO) in its role in public health preparedness, prevention, and control to improve the health and wellbeing of people globally; further,

To prioritize the revision of the ASHP Statement on the Role of Health-System Pharmacists in Public Health.

Background:

In an age of global travel between and among countries the efforts to prevent, control, treat and eradicate diseases and conditions that decrease health and well-being of all peoples are critical to all countries independent of factors such as income and education. Addressing new vectors of disease transmission and behavioral conditions related to lifestyles and environmental conditions continue to provide challenges that need to be addressed. Agencies such as WHO that provide evidence-based warnings, guidelines, education, research and advocacy and collect data to help countries prepare their public health infrastructure are critical in providing all peoples with the tools and resources needed to address critical health issues globally. The current ASHP Statement on the Role of Health-System Pharmacists in Public Health was published in 2008 and should be reviewed and updated.

Suggested Outcome:



The ASHP HOD will approve this new business and emphasize the importance of the role of WHO through its statement on the role of pharmacists in public health.



ASHP Board of Directors, 2020-2021

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INAUGURAL ADDRESS OF THE INCOMING ASHP PRESIDENT

Truth in transformation

Am J Health-Syst Pharm. 2020; XX:0-0

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Thank you for taking a few moments to read this inaugural address. While I wish I were up on stage delivering this as a live speech while we are all gathered together in Seattle at the Summer Meetings, alas, I am not.

In these unprecedented times, let me first wish all of you well in your challenges with the novel coronavirus (SARS-CoV-2) that causes coronavirus disease 2019 (COVID-19). When we first started hearing about the virus just a few (but very long) months ago, it was hard to imagine how this would all play out and continues to play out across the world. Add to this the social upheaval in our country, and it seems like we have been living in a movie or a novel, not our actual lives. Yet here we are.

As I wrote and rewrote this inaugural address over the last several weeks, I realized that nothing I could say would assuage the challenges, fear, anxiety, grief, and other emotions that so many are feeling, working through, or have already overcome.

These events are challenging us to transform personally and professionally in ways that we could never have imagined. Today I'd like to talk to you about transformation and its many forms, how the role of pharmacy services has transformed (and

Sometimes worldwide events challenge us to transform in ways that we would have never thought necessary or even possible. Our profession has undergone rapid transformation over the last few months of almost daily health policy changes.



continues to transform) during the COVID-19 crisis and other crises, and how ASHP is poised to support these growing and evolving pharmacy roles.

Transformation

We certainly all transform over time, sometimes whether we like it or not. Notice that I am using the term "transformation" instead of "change." *Change*, to me at least, is just doing something differently. *Transformation* is beyond that; it is about fully altering your approach, how you see the world, and how you work to grow and develop.

At my core, I am still a farm kid from Minnesota who went to school as part of the Bison family at North Dakota State University and who has lived and worked in South Dakota for over 20 years. But while that core is still intact, my ideas, opinions, thoughts, and approaches are different at this point in my life as a formal leader and administrator, as compared to other points in my life—as a faculty member and critical care specialist, for example. They're certainly different from those of that 4-H kid leading Holsteins (dairy cows) around the yard—and yes, I have pictures, just ask me.

Transformation is something that we will all be faced with as we work through and recover from this pandemic and work through some long-overdue social changes in how we deal with race. Whether it be the virus itself or the economic and system changes that have or will occur in society, we will all be transformed.

Servant leadership

Servant leadership is a key element of transformation, so first and foremost, let's discuss the impact of servant leadership as a stepping-stone to transformation. As I have reflected on the last several weeks, I am reminded of a story that my mother told me about her dad (my grandfather), which was probably the first story I ever really heard (or understood) about gratitude, servant leadership, and ultimately transformation.

Grandpa was always someone who could just figure things out. He worked hard as a farmer and a welder, and he was actively involved in his church and rural community. As a kid, I was pretty convinced he walked on water, so this story has always held a special place in my heart.

As the story goes, as a kid, my mom (her nickname was Boo—it still is) noticed that her dad was always doing something for someone else. People brought things by their farm to be fixed or asked him to come over to help them

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with something, or they borrowed tools or equipment that they needed. But she noticed that it didn't always go both ways. Most of the time, she never saw some of those same people returning the favor. So, one time she asked him, "Dad, why do you keep doing all these things for other people when they don't pay you back?" His answer was, "Well, Boo, I don't worry about that because I know I will get my reward later." What a lesson in servant leadership.

Demonstrating how you should serve others ahead of your interests transforms your approach to life and your family. Grandpa's faith and his servant approach made him who he was, and that's certainly one of the reasons I looked up to him and ultimately transformed into the person I am today.

Servant leadership is what many of us have witnessed, displayed, and championed during these critical times. I'm sure we all have our own stories of servant leadership that have transformed our approach to patient care over these last several months.

ASHP has shared stories from members who were some of the first pharmacists to encounter the trials and challenges of managing COVID-19 case surges in places like New York City and Detroit. There have been daily podcasts dedicated to COVID-19. In addition, through a special live webinar series, ASHP members like Frank Sosnowski, Joe Pinto, Edward Szandzik, and Michael Peters gave the pharmacy community a direct view into the challenges faced by their hospitals at the peak of the surge. Their stories of servant leadership during a time of great challenge were remarkable and provided enormous support to their staff.

ASHP members have demonstrated servantleadership by collaborating with healthcare partners to develop COVID-19 policies, procedures, and protocols for a range of patient needs, including sedation, analgesia, anticoagulation, and antibiotic/antiviral dosing. Many members are working to ensure that the extreme demands of medication preparation and compounding support the immense surge of patients and

significant medication use by patients with COVID-19.

As COVID-19 cases continue to escalate, our members are working as part of the patient care team to select appropriate and sometimes alternative medications, manage sedation targets, and safely adjust dosages to respond to kidney and liver dysfunction in the most critically ill patients. In the face of a highly challenging drug shortages environment, pharmacists are continuously managing the drug supply chain. Further, novel solutions such as curbside prescription pickup optimize physical distancing while allowing pharmacists to provide patient education. Telehealth visits and remote technologies enable pharmacists to support the continuity of care for clinic visits.

These are just a few of the countless ways ASHP members across the country became the servant leaders they needed to be to transform and support teams caring for unprecedented numbers of patients. Pharmacy teams have clearly lived up to the words of George Washington: "Perseverance and spirit have done wonders in all ages."

Personal transformation

Personal transformation, in my opinion, is the first step to broader professional or even societal transformation. Over these last several months, I have often been reminded of the advice of Sister Mary Thomas, our vice president of mission at Avera McKennan Hospital. She has been a steady and guiding presence for so many at Avera over the years.

She encourages us all to be honest with ourselves about who we are as people, as professionals, as servants, and as healthcare providers. We shouldn't make ourselves out to be more than we are, but we also should not sell ourselves short. Simply, she says, "Stand in your truth." This advice has been key for my transformation.

Several months ago, when I first sought her counsel about this inaugural address, she referred me to the book *Transformational Presence* by Alan

Seale. This book was what I needed to read, and I would recommend it to all of you. In his book, Seale challenges you to be the leader you need to be in the moment to ensure the best possible outcome.

Seale uses the words of Theodore Roosevelt—"Do what you can, with what you have, where you are"—to describe how to be the best leader you can be by first intentionally being present in a situation. There's nothing like a worldwide pandemic to cement these words in a person's mind.

He suggests that instead of pushing against changes or obstacles to affect change, we should work with the change or barriers to achieve the outcomes we seek.

Seale reframes Roosevelt's words to state, "If we pause to gain some clarity about where we are and what we have, then what we can do will start to reveal itself." He contends that initial self-reflection and clear assessment can reveal a path to success.

These words not only apply to our daily challenges and constraints, but they may particularly apply to greater issues faced during crises. If we can be who we need to be in the moment to work toward the change that needs to occur, we will be successful.

Transformation of our pharmacy presence

Thomas Jefferson once said, "If you want something you've never had, you must be willing to do something you've never done." The COVID-19 pandemic has demonstrated that pharmacy services are a vital link in the entire healthcare system while challenging us to do things we have never done.

Our ability to compound various products like hand sanitizer and viral transport media when they were in short supply cemented our skills as the can-do experts in compounding and product development.

Our ability to find and recommend alternative therapies when first-line agents became unavailable demonstrated our value in the face of INAUGURAL ADDRESS ASHP REPORT

significant and rapid changes in the marketplace.

Our commitment to evidencebased medication use compelled us to work with our colleagues to direct emerging therapies into appropriate research protocols ensuring optimal patient monitoring and safety while determining overall benefit.

Our physician and nurse colleagues insisted that we be present as part of the care team and planning conversations, further cementing our status as key caregivers.

By demonstrating these skills, we have further established our pharmacy presence. Now, as we adjust to whatever our "new normal" might be as this pandemic progresses and ultimately recedes, it is time for us to *act* on our truth and do some things we've never done.

So, what is our truth?

Our truth is that we are the medication experts on the team, and our presence improves patient safety and optimizes outcomes.

Our truth is that our education and training around medication use is unparalleled in the medical professions.

Our truth is that we are trained to ensure patient safety through evidencebased medication practices.

Our truth is that we have a tremendous opportunity to provide many forms of primary care that our patients need, including testing and medication administration.

Our truth is that we have often been limited because of outdated financial and practice constraints.

Our truth is that opportunities to embrace new models of care are right in front of us. Let us act to seize those opportunities.

Embracing opportunities

We have learned many valuable lessons about what is truly important these last few months. We have learned about the value of networks of friends and colleagues. We have learned about the importance of human interaction. We have learned to be innovative with technology. We have learned which

rules and regulations are beneficial and which ones don't make much sense.

Sometimes worldwide events challenge us to transform in ways that we would have never thought necessary or even possible. Our profession has undergone rapid transformation over the last few months of almost daily health policy changes.

State governors are issuing executive orders that expand pharmacists' ability to provide high-quality care to patients during this crisis. This includes permitting pharmacists to dispense emergency medication refills for an extended time, substitute medications in response to drug shortages, and order point-of-care testing, including ordering and administering COVID-19 tests

You, as ASHP members, and your institutions have transformed to meet the patient care demands of this pandemic. As we emerge from the crisis to assume our new normal, pharmacy services will have demonstrated value in multiple ways. First is our ability to rapidly adapt to changing scenarios while relying on evidence-based practices to help guide conversations about the best use of medications.

Next, we will have demonstrated our core value to the team by rapidly identifying and recommending alternative treatment recommendations. We will have demonstrated our ability to step into public health roles relative to vaccinations, testing, and public education as one of the most accessible healthcare providers.

ASHP supports members

Transformation is something that we will all be faced with as we work through and recover from this pandemic. Throughout the crisis, ASHP has supported members by developing new tools and disseminating important clinical guidance for those working in current hot spots and preparing others for potential patient surges.

ASHP has engaged with federal and state policymakers to advocate for improved access to critical medications and to increase the production and supply of personal protective equipment for pharmacists.

When the worst is behind us, ASHP will be poised to support the growing and evolving role of pharmacy services. ASHP's strong relationships with other professional organizations will further advance our ability to make a difference on national, state, and local levels.

As we individually develop relationships and demonstrate our value, ASHP will serve as our collective voice. ASHP will continue to advance educational and professional initiatives that bring pharmacists closer to our patients.

We will continue to drive the message of transformation through our policy and advocacy processes, and by directly talking with all of you about the resources available through ASHP to assist your transformation.

Act on your truth

Our call to action today is not to develop a brand-new strategy for the future. Nor is it to insist on returning to the exact jobs and roles we once had.

Our call to action is to act on our truth. To recognize the opportunities that are in front of us and seize them—to work with others to effect the changes in the system that we know are needed. To guide and build our future ourselves—not to have others create it for us. To be truly present in the moment as leaders to ensure the best possible outcomes.

My challenge to each of you is to stand in and then act on your truth. Mold the opinions of your patients, your healthcare colleagues, administrators, and the public based on that truth so that we can truly transform ourselves and the pharmacy profession.

Conclusion

To conclude today, I am reminded of the words of Abraham Lincoln: "I'm a success today because I had a friend who believed in me, and I didn't have the heart to let him down."

So, I would like to take a moment to thank those friends who have been so instrumental in my career and my service to ASHP. First, my wife Jodi, the love of my life and my rock of support. Thank you, Jodi, for always being there and supporting me through everything.

I also want to thank my parents, Jim and Betty, who taught me about hard work and sacrifice and encouraged me to be anything I wanted to be. Thank you, Mom and Dad.

And finally, my very long list of mentors, colleagues, and friends in pharmacy. There are so many that I hesitate to try to list names, as you have all meant the world to me, even if you didn't realize or know it at the time. Thank you to all of you.

Thank you for spending some time with me today, and remember to act on your truth! I appreciate everything you are all doing for our patients, for each other, and for society. Thank you, and I look forward to seeing you soon!

Addendum

I originally wrote my inaugural address during the early months of the COVID-19 pandemic and shared it with the ASHP membership on June 8. During the intervening weeks, the events that have unfolded in response to the tragic deaths of George Floyd and too many others express the true urgency for individuals, communities, and organizations of all types to actively listen and work to prioritize actions that lead to change.

The concept of transformation is especially appropriate at this moment in time as we collectively face difficult conversations within our communities and organizations to confront the issue of racism at all levels and seek new pathways for equality and inclusion. At ASHP we are deeply committed to tackling this head-on and have formed a Task Force on Racial Diversity, Equity, and Inclusion to focus on the range of current and historical issues affecting black Americans and the specific actions ASHP can take within its membership mission to address them. This will be a priority during my time as president at ASHP, and I am looking forward

to working with our leadership team and members on this crucial work.

This year my wife Jodi and I have been blessed to have a pharmacy student, and now resident, live in our home. Moe is an international student from The Gambia in West Africa. His experiences, challenges, and stories are very different from ours and have allowed us to see the world through yet another lens. In order to appreciate diversity, we have to be willing to listen and acknowledge different perspectives. Differences are not a threat, and the willingness to accept new ideas and points of view allows us to grow and ultimately fuel our transformation as individuals and professionals.

I hope we can all work to see the world through multiple lenses, and I have high expectations that ASHP will lead the way to a brighter future ahead.

Disclosures

The author has declared no potential conflicts of interest.