

Proceedings of the 66th annual session of the ASHP House of Delegates, June 1 and 3, 2014

PAUL W. ABRAMOWITZ, SECRETARY

The 66th annual session of the ASHP House of Delegates was held at the Mirage Hotel and Convention Center, in Las Vegas, Nevada, in conjunction with the 2014 Summer Meeting.

First meeting

The first meeting was convened at 1:00 p.m. Sunday, June 1, by Chair of the House of Delegates James A. Trovato. Chair Trovato introduced the persons seated at the head table: Kathryn R. Schultz, Immediate Past President of ASHP and Vice Chair of the House of Delegates; Gerald E. Meyer, President of ASHP and Chair of the Board of Directors; Paul W. Abramowitz, Chief Executive Officer of ASHP and Secretary of the House of Delegates; and Joy Myers, Parliamentarian.

Chair Trovato welcomed the delegates and 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. A quorum was present, including 200 delegates representing 48 states, the District of Columbia, and Puerto Rico (no delegates from Hawaii or Delaware were present), 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 Trovato reminded delegates that the report of the 65th annual session of the ASHP House of Delegates had been published on the ASHP Web site and had been distributed to all delegates. Delegates had been advised earlier to review this report. The proceedings of the 65th House of Delegates session were received without objection.

Chair Trovato called on Robert Adamson for the report of the Committee on Nominations (Appendix II).^a Nominees were presented as follows:

President-elect

John A. Armitstead, M.S., R.Ph., FASHP, System Director of Pharmacy Services, Lee Memorial Health System, Fort Myers, FL

Lisa M. Gersema, Pharm.D., M.H.A., BCPS, FASHP, Director of Pharmacy United Hospital, part of Allina Health St. Paul, MN

Chair, House of Delegates (2014–2015)

Michael F. Powell, B.S. Pharm., M.S., FASHP, Executive Director, Pharmaceutical & Nutrition Care, The Nebraska Medical Center, and Associate Professor and Associate Dean for Hospital Affairs, The University of Nebraska Medical Center College of Pharmacy, Omaha, NE

James A. Trovato, Pharm.D., M.B.A., BCOP, FASHP, Associate Professor, University of Maryland School of Pharmacy, Baltimore, MD

Board of Directors (2015–2018)

Timothy R. Brown, Pharm.D., BCACP, FASHP, Director of Clinical Pharmacotherapy in Family Medicine, Akron General Medical Center for Family Medicine, Akron, OH

Michael B. Cockerham, Pharm.D., M.S., FASHP, Professor and Associate Dean for Academic Affairs, University of Louisiana at Monroe School of Pharmacy, Shreveport, LA

Debra L. Cowan, Pharm.D., FASHP, Director of Pharmacy, Angel Medical Center, Franklin, NC

Lea S. Eiland, Pharm.D., BCPS, FASHP, Clinical Professor and Associate Department Head, Auburn University Harrison School of Pharmacy, Auburn, AL

A “Meet the Candidates” session to be held on Monday, June 2, was announced. Chair Trovato announced the candidates for the executive committees of the five sections of ASHP.

Policy committee reports. Chair Trovato outlined the process used to generate policy committee reports (Appendix III). He announced that the recommended policies from each council would be introduced as a block. He further advised the House that any delegate could raise questions and discussion without having to “divide the question” and that a motion to divide the question is necessary only when a delegate desires to amend a specific proposal or to take an action on one proposal separate from the rest of the report; requests to divide the question are granted automatically unless another delegate objects. Chair Trovato reminded delegates that policies not separated by dividing the question would be voted on en bloc before the House considered the separated items.

Chair Trovato 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: italic 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; see that section of these Proceedings for the final disposition of amended policies.)

Kelly M. Smith, Board Liaison to the Council on Pharmacy practice, presented the Council’s Policy Recommendations A through F.

*A. *Standardization of Oral Liquid Medication Concentrations*
To advocate for the development of nationally standardized drug concentrations for oral liquid medications; further,

To encourage ~~hospitals and health systems~~ *all prescribers and dispensers of medications* to standardize concentrations of oral liquid medications; further,

To ~~support the goal of developing standardized doses for pediatric oral liquid medications and, when appropriate, for adult doses;~~ further,

To promote effective instruction of patients and caregivers on how to properly measure and administer oral liquid medications.

*B. *Safe Use of Radiopharmaceuticals*

To affirm that radiopharmaceuticals require the same standards for safe medication use as other medications, including but not limited to standards for procurement, storage and control, prescribing, ~~handling~~, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, disposal, and formulary consideration as other medications; further,

To advocate that pharmacy departments, in cooperation with departments of nuclear medicine, and radiology, and radiation safety, provide oversight of radiopharmaceuticals to assure safe use; further,

To advocate for incorporation of information on radiopharmaceuticals into the pharmacy school curriculum and increased pharmacy continuing education on radiopharmaceuticals.

*C. *Pharmacist’s Role on Ethics Committees*

To advocate that pharmacists should be included as members of hospital and health-system ethics committees and ~~be involved in ethics consultations when appropriate;~~ further,

To encourage pharmacists to actively seek ethics consultations as appropriate; further,

To encourage pharmacists serving on ethics committees to seek advanced training in health care ethics.

D. *Safe Use of Fentanyl Transdermal Patches*

To advocate for enhanced consumer education and product safety requirements for fentanyl transdermal system patches; further,

To encourage manufacturers of fentanyl transdermal system patches to collaborate with pharmacists and other stakeholders to identify and implement packaging, labeling, and formulation changes that prevent accidental exposure and facilitate safe disposal.

*E. *Automatic Stop Orders*

To advocate that the Centers for Medicare & Medicaid Services (1) ~~revise~~ *remove* the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice; further,

To affirm that *the requirement for automatic stop orders for all medications is* are a potential source of medication errors and patient harm; further,

To encourage pharmacists to participate in interprofessional efforts to establish standardized methods to assure appropriate duration of therapy.

F. *International System of Units*

To discontinue ASHP policy 8612, which reads:

To not advocate, at this time, adoption of the International System of Units (SI units) as the exclusive labeling for drug dosages and concentrations; further,

To urge labelers to include: (1) units of mass, volume, or percentage concentrations and (2) moles or millimoles in labeling until the health professions and the public can be educated and be comfortable with use of SI units in prescribing and labeling drug products.

Steven S. Rough, Board Liaison to the Council on Public Policy, presented the Council's Policy Recommendations A through E.

**A. Federal and State Regulation of Compounding*

To advocate that the applicable compendial standards of the United States Pharmacopeia be included in state and federal laws and regulations that govern compounding by any health professional; further,

To advocate for *mandatory* state registration of compounding facilities (e.g., pharmacies, physician offices, clinics, ambulatory surgery centers) that provide products for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders; further,

To advocate for *mandatory* Food and Drug Administration registration and current good manufacturing practices requirements for outsourcing facilities that compound and sell products without patient-specific prescriptions across state lines; further,

To advocate that registration of compounding facilities at either the federal or state level include registration fees that are used to improve patient safety and care by educating state and federal inspectors, improving the frequency and effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate for improved patient safety and care through education of regulatory inspectors, increased frequency and improved effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate that state and federal agencies develop standardized definitions and nomenclature relating to sterile and nonsterile compounding, including but not limited to definitions of compounding, manufacturing, repackaging, and relabeling.

**B. 340B Drug Pricing Program Sustainability*

To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would ~~expand eligibility~~ *optimize access* to the 340B program in accordance with ~~Health Resources and Services Administration oversight~~ and the intent of the program; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators ~~about the information technology and other resources required to support 340B program compliance and documentation, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation;~~ further,

To encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

**C. State Prescription Drug Monitoring Programs*

To advocate for *mandatory* uniform state prescription drug monitoring programs that collect *real-time* ~~timely~~, relevant, and standard information *from all dispensing outpatient entities* about controlled substances *and monitored* prescriptions; further,

To advocate that the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further,

To advocate that such programs be structured as part of electronic health records and exchanges to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment; further,

To advocate for *full* interstate integration to allow for access by prescribers, pharmacists, and other *qualified designees* ~~practitioners~~ across state lines; further,

To advocate for federal and state funding to establish and administer these programs; further,

To promote research, education, and implementation of best practices in prescription drug monitoring programs.

D. Approval of Biosimilar Medications

To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,

To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,

To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; further,

To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

E. Management of Blood Products and Derivatives

To discontinue ASHP policy 9919, which reads:

To strongly encourage the computer software industry to provide data fields for lot number, expiration date, and other necessary and appropriate information for blood products and derivatives and biologicals, in order to facilitate compliance with regulatory requirements concerning the use of these products, particularly with respect to recalls or withdrawals.

Larry C. Clark, Board Liaison to the **Council on Therapeutics**, presented the Council's Policy Recommendations A through D.

**A. Access to Oral Contraceptives Through an Intermediate Category of Drug Products*

To advocate that *oral contraceptives* these products be provided only under conditions that ensure safe use, including the availability of counseling to ensure appropriate self-screening and product selection; further,

To support expanded access to *these products oral contraceptives* through an *proposed* intermediate category of drug products, *as described by ASHP policy*, that ~~do not require a prescription~~ but are available only would be available from all pharmacists and licensed health care professionals (*including pharmacists*) who are authorized to prescribe medications; further,

To advocate that the proposed reclassification of these products be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised *and that pharmacists are reimbursed for the clinical services provided.*

B. Expedited Pathways for FDA Drug Approval

To support the use of expedited pathways for Food and Drug Administration (FDA) approval of new drugs that expand access to innovative therapies while protecting patient safety; further,

To advocate for the development of unique labeling requirements that would be used on an interim basis to identify products approved by these pathways in order to increase awareness of data limitations and guide clinician use of these drugs until additional evidence becomes available; further,

To advocate that the FDA be diligent in enforcing postmarketing commitments for drug products approved via expedited pathways, including utilizing its existing authority to enforce penalties when these requirements are not met; further,

To encourage research to evaluate the impact of expedited pathways on drug product development and patient care, including drug development timelines and costs, overall health care costs, patient access to care, and the effectiveness and safety of these therapies.

C. FDA Oversight of Laboratory-Developed Tests

To advocate that the Food and Drug Administration be granted increased authority to regulate laboratory-developed tests as medical devices, including tests used for pharmacogenetic testing; further,

To support development of a risk-based framework for regulatory oversight of laboratory-developed tests that promotes innovation while providing a mechanism to ensure that test results are reliable, reproducible, and clinically relevant; further,

To encourage expanded availability of commercially marketed pharmacogenetic tests that would be available for use by laboratory and health care professionals to guide drug therapy.

**D. Ensuring Effectiveness, Safety, and Access to Orphan Drug Products*

To encourage continued research on and development of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of these drug products for approved and off-label indications; further,

To advocate that the Food and Drug Administration maintain a publicly available and comprehensive list of orphan drug products and their approved indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products.

Thomas J. Johnson, on behalf of Paul W. Bush, Board Liaison to the **Council on Education and Workforce Development**, presented the Council's Policy Recommendations A through D.

**A. Cultural Competency and Cultural Diversity*

To promote the development of cultural competency of pharmacy educators, practitioners, residents, students, and technicians; further,

To educate providers on the importance of providing culturally congruent care to achieve quality care and patient engagement; further,

To foster awareness of the impact that an ethnically and culturally diverse workforce has on improving health care quality.

B. Credentialing, Privileging, and Competency Assessment

To support the use of post-licensure credentialing, privileging, and competency assessment to practice pharmacy as a direct patient-care practitioner; 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 independently responsible for maintaining competency to practice in direct patient care.

C. Education About Patient Safety in the Medication-Use Process

To discontinue ASHP policy 0914, which reads:

To encourage colleges of pharmacy to include instruction on patient safety throughout the medication-use process in the didactic curriculum and during experiential education.

D. ASHP Statement on Continuing Education

To discontinue the ASHP Statement on Continuing Education.

Kathleen S. Pawlicki, Board Liaison to the **Council on Pharmacy Management**, presented the Council's Policy Recommendations A through F.

**A. Pharmacy Department Interface with Business Partners*

To recognize that a key objective of pharmacy departments is to provide comprehensive medication management across the continuum of patient care; further,

To recognize that it is optimal from a continuity of care, quality, financial, and risk management perspective to maintain all medication-related clinical and business activities within the health-system pharmacy enterprise; further,

To encourage pharmacy leaders to proactively evaluate potential business partnerships against this objective; further,

To recognize that hospitals and health-system pharmacy leaders must ensure that business partners meet all applicable patient safety and accountability standards; further,

To provide education and tools for pharmacy leaders to aid in the evaluation of and development of business partnerships; further,

To educate health-system administrators on the importance of pharmacy leadership in evaluating and developing pharmacy-related business partnerships; further,

To encourage health-system pharmacy leaders to consider evolving health care financing systems when evaluating and developing business partnerships.

B. Integration of Pharmacy Services in Multifacility Health Systems

To advocate that pharmacists are responsible for organizational efforts to standardize and integrate pharmacy services throughout the entire pharmacy enterprise in multifacility health systems and integrated delivery networks; further,

To educate health-system administrators about the importance of pharmacy leadership in setting system-wide policy regarding the safe and effective use of medications; further,

To advocate for the regulations and resources needed to support efforts to achieve optimal patient health outcomes in multifacility organizations.

**C. Risk Assessment of Health Information Technology*

To urge hospitals and health systems to *directly involve the Department of Pharmacy* to perform appropriate risk assessment before new health information technology (HIT) is implemented, ~~or~~ existing HIT is upgraded, *and as part of the continuous evaluation of current HIT performance*; further,

To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,

To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes; *further,*

To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

**D. Documentation of Patient-Care Services in the Permanent Health Record*

To advocate for public and organizational policies that support pharmacist documentation of patient-care services in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of pharmacist patient care on patient outcomes and total cost of care; further,

To advocate that electronic health records be designed *with a common documentation space to accommodate all health care team members and support the communication needs of pharmacy documentation by pharmacists.*

E. Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient-Assistance Programs

To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drugs used in inpatient settings; further,

To encourage pharmacists and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

F. Fostering Pharmacy Leadership

To discontinue ASHP policy 9901, which reads:

To encourage pharmacy managers to serve as mentors to their staff, pharmacy students, pharmacy residents, and peers in a manner that fosters the development of future pharmacy leaders.

Kathryn R. Schultz, on behalf of Paul W. Bush, Board Liaison to the Section of Clinical Specialists and Scientists, then moved adoption of the Section's policy recommendation, "ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics." Delegates voted to approve the recommendation.

President Gerald Meyer then presented the Board's proposed changes to ASHP Bylaws and Procedures of the House (Appendix IV). Delegates approved most of the proposed bylaws changes, amending two sections as follows.

3.1.1. Active Members: Pharmacists licensed by any state, district, or territory of the United States who have paid dues as established by ASHP; *practice in the 50 jurisdictions of the United States, the District of Columbia, or Puerto Rico;* and who support the purposes of ASHP as stated in the Article Third of the ASHP Charter.

(Note: *italic text* is Board-proposed language; ~~strikethrough~~ is House amendment.)

7.4.3. The Chair shall appoint a Committee on Nominations consisting of seven active members *who shall have been del-*

egates to the House of Delegates within the last five years at the time of their appointment to serve as a Committee of the House who shall be delegates to the House of Delegates at the time of their appointment to serve as a Committee of the House. The Committee shall solicit names of possible candidates for office using such means as it determines to be appropriate.

(Note: ~~strikethrough~~ is Board-proposed deletion; *italic* is House-approved amendment.)

Statements of Candidates for Chair of House and Treasurer.

Candidates for the positions of Chair of the House of Delegates and Treasurer made brief statements to the House of Delegates.

Report of Treasurer. Philip J. Schneider presented the report of the Treasurer. There was no discussion, and the delegates voted to accept the Treasurer's report (Appendix V).

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

The meeting adjourned at 4:15 p.m.

Second meeting

The second and final meeting of the House of Delegates session convened on Tuesday, June 4, at 4:00 p.m. A quorum was present.

Election of House Chair

Vice Chair Schultz announced the appointment of alternate delegates as tellers to monitor and report on the election of the Chair of the House of Delegates. Those appointed were Paul Barrett (ME), James Hoffman (TN), Leigh Briscoe-Dwyer (NY), Anne Policastro (KY), Jennifer Phillips (IL), and Barbara Giacomelli (SOPIT). Vice Chair Schultz instructed tellers and delegates on the process for electronic voting for the office of House Chair. After the voting process, tellers left the assembly to prepare their report while the business of the House proceeded.

Report of President and Chair of the Board. President Meyer updated and elaborated upon various ASHP initiatives. There was no discussion, and the delegates voted to accept the report of the Chair of the Board (Appendix VII).

Report of Chief Executive Officer. Paul W. Abramowitz presented the report of the Chief Executive Officer (Appendix VIII).

Board of Directors duly considered matters. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of 4, to "duly consider" the policies and proposed Bylaws changes amended at the first meeting. The Board reported on the 13 professional policies and two sections of the ASHP Bylaws that were amended at the first House meeting. The Board accepted all amendments to the Bylaws and 12 of the 13 amendments to policy recommendations, with minor editorial changes to two as follows:

A. Standardization of Oral Liquid Medication Concentrations

To advocate for the development of nationally standardized drug concentrations for oral liquid medications; further,

To encourage all health care providers and organizations to standardize concentrations of oral liquid medications; further,

To promote effective instruction of patients and caregivers on how to properly measure and administer oral liquid medications.

C. Risk Assessment of Health Information Technology

To urge hospitals and health systems to directly involve departments of pharmacy to perform appropriate risk assessment before new health information technology (HIT) is implemented or existing HIT is upgraded, and as part of the continuous evaluation of current HIT performance; further,

To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,

To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes; further,

To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

The Board declined to accept the House amendments to Council on Pharmacy Management Policy Recommendation A, "Pharmacy Department Interface with Business Partners," and proposed modified language that combined the first two clauses of the original to achieve the intent of Delegates, as follows:

To recognize that a key objective of pharmacy departments is to provide comprehensive medication management across the continuum of patient care, and that pharmacy leaders should proactively evaluate potential business partnerships against this objective; further,

To recognize that hospitals and health-system pharmacy leaders must ensure that business partners meet all applicable patient safety and accountability standards; further,

To provide education and tools for pharmacy leaders to aid in the evaluation of and development of business partnerships; further,

To educate health-system administrators on the importance of pharmacy leadership in evaluating and developing pharmacy-related business partnerships; further,

To encourage health-system pharmacy leaders to consider evolving health care financing systems when evaluating and developing business partnerships.

The House voted to accept the Board-proposed modified language.

New Business. Chair Trovato announced that, in accordance with Article 7 of the Bylaws, there were no items of New Business to be considered.

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

Recognition. Chair Trovato recognized members of the Board who were continuing in office (Appendix IX). 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 Trovato presented Immediate Past President Meyer with an inscribed gavel commemorating his term of office. Dr. Meyer recognized the service of Chair Trovato as Chair of the House of Delegates and a member of the Board of Directors.

Chair Trovato recognized Kathryn Schultz's years of service as a member of the Board, in various presidential capacities, as Chair of the Board, and as Vice Chair of the House of Delegates.

Chair Trovato then installed the chairs of ASHP's sections and forums: Melanie Dodd, Section of Ambulatory Care Practitioners; Christopher Betz, Section of Clinical Specialists and Scientists; Daniel Degnan, Section of Inpatient Care Practitioners; Barbara Giacomelli, Section of Pharmacy Informatics and Technology; Thomas Kirschling, Section of Pharmacy Practice Managers; Brandon Shank, New Practitioners Forum; and Emily Carrell, Pharmacy Student Forum.

Chair Trovato then recognized the remaining members of the executive committees of sections and forums.

Results of Election. Chair Trovato relinquished the gavel to Vice Chair Schultz to report the results of the election. Vice Chair Schultz then announced that James A. Trovato had been elected as Chair of the House.

Installation. Vice Chair Schultz then installed Christene M. Jolowsky as President of ASHP, Don Letendre and Raneé Runnebaum as members of the Board of Directors (Appendix IX), and James A. Trovato as Chair of the House of Delegates. (See Appendix X for the Inaugural Address of the Incoming President.)

Adjournment. The 66th annual session of the House of Delegates adjourned at 6:00 p.m.

^aThe Committee on Nominations consisted of Robert Ad-
amson, Chair (NJ); Stan Kent, Vice Chair (IL); Leigh Briscoe-
Dwyer (NY); Patricia Knowles (GA); Tommy Mannino (LA);
Jamie Sinclair, (MN); and Donna Soflin (NE).

HOUSE OF DELEGATES
James Trovato, Chair
Kathryn Schultz, Vice Chair
Las Vegas, Nevada
June 1 and June 3, 2014

OFFICERS AND BOARD OF DIRECTORS			
Gerald Meyer, President			
Christene Jolowsky, President-Elect			
Kathryn Schultz, Immediate Past President			
James Trovato, Chair, House of Delegates			
Philip Schneider, Treasurer			
Paul Abramowitz, Chief Executive Officer			
Kelly Smith, Board Liaison, Council on Pharmacy Practice			
Paul Bush ² , Board Liaison, Council on Education and Workforce Development			
Kathleen Pawlicki, Board Liaison, Council on Pharmacy Management			
Steven Rough, Board Liaison, Council on Public Policy			
Thomas Johnson, Board Liaison, Commission on Affiliate Relations			
Larry Clark, Board Liaison, Council on Therapeutics			
PAST PRESIDENTS			
Roger Anderson	Stanley Kent		
Daniel Ashby	Lynnae Mahaney		
Jan Carmichael ²	James McAllister III		
Kevin Colgan	John Murphy		
Debra Devereaux	Philip Schneider		
Fred Eckel	Thomas Thielke		
Rebecca Finley	Sara White		
Diane Ginsburg	T. Mark Woods		
Harold Godwin	David Zilz		
Mick Hunt Jr.			
Marianne Ivey			
STATE	DELEGATES		
Alabama (3)	Kimberley Benner Brenda Denson Whitney White		
Alaska (2)	Shawn Bowe Ashley Schaber		
Arizona (3)	Melinda Throm Burnworth Sandra Leal Carol Rollins		
Arkansas (2)	Zhiva Brown Lanita White ¹ Rayanne Story ²		

¹Sat in Sunday House Meeting only
²Sat in Tuesday House Meeting only

STATE	DELEGATES
California (8)	Annet Arakelian Charles Daniels Victoria Ferraresi Jerry Gonzales Steven Gray Brian Kawahara Elaine Law Julie Lenhart
Colorado (3)	Jennifer Davis Ashley Mains Joel Marrs
Connecticut (3)	Molly Leber Lorraine Lee
Delaware (2)	
Florida (5)	John Armistead Deborah Brown Christine Gegeckas E. Richard Kessler Antonia Zapantis
Georgia (3)	Megan Freeman Michael Melroy Majorie Phillips
Hawaii (2)	
Idaho (2)	Dawn Berheim Paul Driver
Illinois (5)	Ann Jankiewicz Despina Kotis Miriam Mobley-Smith Christina Rivers Andrew Donnelly
Indiana (3)	Daniel Degnan John Hertig Amy Hyduk
Iowa (3)	Jack Kampf Lisa Mascardo David Weetman
Kansas (3)	Gregory Burger Amber Lucas Christopher Bell
Kentucky (3)	Margo Ashby Michael Berger Stephanie Sutphin
Louisiana (3)	Michael Cockerham Charles Jastram ¹ Tommy Mannino ² Roxie Stewart

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STATE	DELEGATES
Maine (2)	Brian Marden Tyson Thornton
Maryland (4)	MaryBeth Kazanas Rachel Kruer Kristine Parbuoni Meghan Swarthout
Massachusetts (4)	Ernest Anderson Nicole Clark Margarita DiVall Ross Thompson
Michigan (4)	Gary Blake Jesse Hogue Peggy Malovrh Paul Walker
Minnesota (3)	Matthew Ditmore Kristi Gullickson John Pastor
Mississippi (2)	Wesley Pitts Laurie E. Warrington
Missouri (3)	Nicole Allcock Joel Hennenfent Amy Sipe
Montana (2)	Lonnye Finneman Kerry Haney
Nebraska (3)	Michele Faulkner Donna Soflin Jerome Wohleb
Nevada (2)	Adam Porath
New Hampshire (2)	Karen Michaud Elizabeth Wade
New Jersey (4)	Robert Adamson Luigi Brunetti Timothy Reilly Daryl Schiller
New Mexico (2)	Stephen Adams Melanie Dodd ²
New York (5)	Debra Feinberg Stephanie Seyse Elizabeth Shlom Mark Sinnett Frank Sosnowski
North Carolina (4)	Stephen Eckel Lynn Eschenbacher Jenna Huggins Dennis Williams

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STATE	DELEGATES
North Dakota (2)	Joan Johnson Amber Olek
Ohio (5)	Kathleen Donley Dale English, II Margaret Huwer Karen Kier Julie Zaucha
Oklahoma (3)	Tracy Hegemann Lisa Mayer Darin Smith
Oregon (3)	Kristina Butler Kristine Marcus Michelle Murray
Pennsylvania (5)	Richard Demers Nishaminy Kasbekar Patricia Kienle Richard Pacitti Jean Scholtz
Puerto Rico (2)	Gizelle Rivera
Rhode Island (2)	Ewa Dzwierzynski Andrea Haron
South Carolina (3)	Christopher Fortier Natasha Nicol Robert Spires
South Dakota (2)	Katie Hayes Tadd Hellwig
Tennessee (3)	Donald Branam Christopher Finch Casey White
Texas (6)	Lourdes Cuellar Diane Fox Harold Habeger Julie Nelson Lance Ray James Wilson
Utah (3)	Jason Braithwaite Erin Fox Linda Tyler
Vermont (2)	Kevin Marvin Jeffrey Schnoor
Virginia (4)	Lisa Deal Emily Dyer Rodney Stiltner Robert Stoneburner
Washington, D.C. (2)	Mary Bingham Vaiyapuri Subramaniam

¹Sat in Sunday House Meeting only
²Sat in Tuesday House Meeting only

STATE	DELEGATES
Washington State (4)	William Jessee Kathryn Renouard-Brown Steven Riddle Roger Woolf
West Virginia (2)	Justin Hare Carol Woodward
Wisconsin (4)	Terry Audley Arlene Iglar Ryan Miller Michelle Thoma
Wyoming (2)	Linda Gore-Martin Matthew Stanton
SECTIONS AND FORUMS	DELEGATES
Ambulatory Care Practitioners	Melanie Dodd ¹ Seena Haines ²
Clinical Specialists and Scientists	Jill Bates
Inpatient Care Practitioners	Noelle Chapman
Pharmacy Informatics and Technology	Michael Schlesselman
Pharmacy Practice Managers	Todd Karpinski
New Practitioners Forum	Brandon Shank
Pharmacy Student Forum	Emily Carrell
FRATERNAL	DELEGATES
Veterans Affairs	Julie Groppi

¹Sat in Sunday House Meeting only
²Sat in Tuesday House Meeting only



The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

HOUSE OF DELEGATES

REPORT OF THE

COMMITTEE ON NOMINATIONS

June 1, 2014

Las Vegas, Nevada

Rob Adamson (Chair), New Jersey
Stan Kent (Vice Chair), Illinois
Leigh Briscoe-Dwyer, New York
Patricia Knowles, Georgia
Tommy Mannino, Louisiana
Jamie Sinclair, Minnesota
Donna Soflin, Nebraska

ASHP COMMITTEE ON NOMINATIONS

Mister Chair, Fellow Delegates:

The Committee on Nominations consists of seven members of the Society 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. It is a difficult job.

Selection of nominees for Society office involves a series of 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 health-system pharmacy practice.

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, and nominees for Chair of the House of Delegates must also be able to perform the special duties set forth in article 7 of the Bylaws.

The more difficult part of the Committee's work is to assess those intangible qualities of leadership, vision, engagement, and 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; and
- Communication and consensus building skills.

In the case of the nominees for the office of Chair of the House of Delegates, the Committee must also assess the ability of the nominees to represent the interests of the House of Delegates on the Board of Directors and to be an effective facilitator of the policy process.

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 the Society's needs. The Committee has met twice in person since the last session of the House of Delegates: on December 10, 2013, at the Midyear Clinical Meeting in Orlando, Florida; and on April 17, 2014, at ASHP headquarters; and met once via teleconference. Review of nominees' materials was conducted continuously between March and April 2014 solely via secure electronic transmissions. This process has been reviewed for quality improvement and will be repeated for the 2014–2015 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 the ASHP *Intersections*, online ASHP NewsLink bulletins, and the ASHP website to submit nominations for the Committee's consideration. Nominations from state affiliate societies were solicited through special mailings and the "state affiliate" edition of the online NewsLink service. At the 2013 Midyear Clinical Meeting, the Chair and Secretary made themselves available to receive nominations personally in a location and at a time that were publicized in ASHP news publications and correspondence.

For the upcoming Midyear Clinical Meeting in Anaheim, California, the Committee would like interested individuals and state affiliates to submit their written expression of interest and support to the ASHP onsite office no later than noon on Tuesday, December 9, 2014.

Based upon recommendations from membership, state affiliates, and ASHP staff, the Committee contacted over 200 individuals identified as possible candidates; 96 responded. Some individuals were invited to accept consideration for more than one office. Of all nominees who responded to the invitation to place themselves in nomination, the breakdown by office is as follows:

PRESIDENT-ELECT: 6 accepted; 58 declined.

BOARD OF DIRECTORS: 33 accepted; 58 declined.

CHAIR, HOUSE OF DELEGATES: 8 accepted; 58 declined.

A list of candidates that were slated was provided to delegates following the Committee's meeting on April 17, 2014.

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

President-Elect

John A. Armitstead, M.S., R.Ph., FASHP (Fort Myers, FL)

Lisa M. Gersema, Pharm.D., M.H.A., BCPS, FASHP (St. Paul, MN)

Board of Directors

Timothy R. Brown, Pharm.D., BCACP, FASHP (Akron, OH)

Michael B. Cockerham, Pharm.D., M.S., FASHP (Shreveport, LA)

Debra L. Cowan, Pharm.D., FASHP (Franklin, NC)

Lea S. Eiland, Pharm.D., BCPS, FASHP (Auburn, AL)

Chair, House of Delegates

Michael F. Powell, B.S. Pharm., M.S., FASHP (Omaha, NE)

James A. Trovato, Pharm.D., M.B.A., BCOP, FASHP (Baltimore, MD)

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

PRESIDENT-ELECT

JOHN A. ARMITSTEAD, M.S., R.Ph., FASHP (239-343-6490; john.armitstead@leememorial.org) is System Director of Pharmacy Services, Lee Memorial Health System, Fort Myers and Cape Coral, Florida. John obtained an M.S. in Hospital/Clinical Pharmacy at Ohio State University and completed a Pharmacy Residency at Riverside Methodist Hospital. He received a B.S. in Pharmacy from Ohio Northern University.

John leads pharmacy care serving Southwest Florida in a four-hospital health system with cancer center, pediatric hospital, health plan, and community pharmacies. A continuum of services is provided with a mission of “Optimizing Patient Outcomes through Interdisciplinary Medication Management.”

Previously serving patients through advancing practice in Ohio and Kentucky, John served as President of the KSHP and OSHP and is a Latiolais Award winner. He recently completed serving on the Board of Directors of ASHP, has served on ASHP councils/committees, is active in the FSHP, and was a founding member of the Florida Residency Conference.

LISA M. GERSEMA, Pharm.D., M.H.A., BCPS, FASHP (651-241-8879; lisa.gersema@allina.com) is Director of Pharmacy and the Residency Program Director at United Hospital in St. Paul, Minnesota. Previously, she was a clinical decentral pharmacist and Assistant Director of Clinical Pharmacy Operations at Saint Luke’s Hospital in Kansas City. She completed her B.S., Pharm.D., and Fellowship in Clinical Pharmacology at the University of Iowa and received her M.H.A. from Simmons College.

Lisa’s career has focused on advancing pharmacy practice in a decentralized clinical care model. An emphasis has been to encourage staff to advance their professional and leadership skills.

Her ASHP service includes ASHP Board of Directors, Chair of the Council on Pharmacy Practice, member of the Commission on Therapeutics, and ASHP state delegate. She served as President and Treasurer of the Minnesota Society of Health-System Pharmacists. Lisa was honored with MSHP’s Hugh Kabat Award and the Hallie Bruce Award (MSHP’s highest honor).

BOARD OF DIRECTORS

TIMOTHY R. BROWN, Pharm.D., BCACP, FASHP (330-344-1797; timothy.brown@akrongeneral.org) is Director of Clinical Pharmacotherapy in Family Medicine at Akron General Medical Center for Family Medicine and Professor at Northeast Ohio Medical University. He received his degree from Campbell University School of Pharmacy with residency training at the Medical College of Virginia. His current practice model was one of the first to showcase a pharmacist providing primary care for a wide range of patients. He is a leader in Ambulatory Care and is co-editor of a popular “How-to” book.

Brown is Past President of the Ohio Society of Health-System Pharmacists and Past Chair and Director-at-Large of SACP. Tim has served as an ASHP leader in multiple ways, including councils, committees, conference planning and recently as a member of the Ambulatory Care Summit Steering Committee and Advisory Group. He has received numerous teaching awards and been honored for his community service promoting healthcare literacy.

MICHAEL B. COCKERHAM, Pharm.D., M.S., FASHP (318-632-2007; mcocke@lsuhsc.edu) is Associate Dean for Academic Affairs, University of Louisiana at Monroe College of Pharmacy. He directs the professional curriculum, student affairs and experiential education. He serves on the Louisiana Collaborative Practice Advisory Board, the Louisiana Pharmacy Congress and NAPLEX Review Committee. Before academics he served as a clinical oncology pharmacist with the VA and practiced pharmacy with a large chain. He received his Pharm.D. from Idaho State University, B.S. Pharm. and M.S. from ULM. He received advanced oncology training at the VA in San Antonio, TX.

Mike served ASHP on the Council on Education and Workforce Development, Chair of Nominations Committee, Clinical Skills Competition Judge and as Louisiana Delegate since 2005. He is Past President of the Louisiana Society of Health-System Pharmacists and has held other elected positions within LSHP. He has received LSHP’s Pharmacist of the Year and highest service awards.

BOARD OF DIRECTORS (continued)

DEBRA L. COWAN, Pharm.D., FASHP (828-349-6851; debby.cowan@msj.org) received her Bachelor of Science in Pharmacy with honors from the University of New Mexico and her Doctor of Pharmacy degree from the University of Colorado. She attended the ASHP Foundation's Pharmacy Leadership Institute in 2011. Currently she is serving as Adjunct Faculty with the University of North Carolina at Chapel Hill Eshelman School of Pharmacy.

Dr. Cowan serves as Director of Pharmacy at Angel Medical Center, a critical access hospital, which is part of the Mission Health System in North Carolina. She has been a small and rural hospital pharmacist for 34 years, with 26 of those years spent as director.

Dr. Cowan is a long-time member of the American Society of Health-System Pharmacists, with experience on many committees, councils, and workgroups including chairmanship of the Section of Inpatient Care Practitioners (SICP) Executive Committee, Small and Rural Hospital Advisory group, and SICP Committee on Nominations.

LEA S. EILAND, Pharm.D., BCPS, FASHP (256-551-4445; eilanls@auburn.edu) is a Clinical Professor and Associate Department Head of Pharmacy Practice, Auburn University Harrison School of Pharmacy; Clinical Associate Professor of Pediatrics, University of Alabama at Birmingham School of Medicine, Huntsville Regional Medical Campus; and pediatric pharmacist, UAB Huntsville Pediatric Clinic. She received her Pharm.D. from The University of Texas and completed an ASHP-accredited pediatric specialty residency at Texas Tech University.

Lea has been an active member of ASHP, serving the SCSS as Chair and Director-at-Large of the Executive Committee and a Network Facilitator. She has served on the EVP/CEO Search and Screen Committee; Chair of the Council on Education and Workforce Development; Task Force on Pharmacy's Changing Demographics; and state delegate. She has published in *AJHP* and serves as a reviewer. Lea is a Past-President of AISHP, Auburn student chapter faculty advisor and received the AISHP Pharmacist of the Year Award.

CHAIR, HOUSE OF DELEGATES

MICHAEL F. POWELL, B.S. Pharm., M.S., FASHP (402-559-9555; mpowell@nebraskamed.com) is Executive Director, Pharmaceutical and Nutrition Care at The Nebraska Medical Center, and Associate Dean, Hospital Affairs, UNMC College of Pharmacy. Mr. Powell received B.S. and M.S. degrees in pharmacy from The Ohio State University (1974) and the University of Maryland (1977), respectively. He completed a hospital pharmacy residency at the University of Maryland Hospital from 1974-76. He has held positions as Assistant Director, Associate Director, and Director of Pharmacy positions in San Antonio, Texas; Detroit, Michigan; and Cleveland, Ohio. He has served as an elected officer and committee member in local and state pharmacy associations. A member of ASHP for more than 35 years, Mr. Powell has chaired both Special Interest Groups and Advisory Working Groups and served both as an elected and alternate delegate. Most recently, he completed a term as Chair of the Section of Pharmacy Practice Managers.

Mr. Powell's statement:

Pharmacy's societal role is medication safety! As a discipline, we are focused on quality medication therapy outcomes. Society demands quality outcomes from health care encounters. The public increasingly depends on information to make their selection of providers and the professions they turn to for health care. Medications are the single most frequently utilized health care intervention. If patients are to have access to the care of pharmacists and we are to gain recognition as providers, we cannot simply rely on legislation. We must be as innovative and forward thinking as possible, by creating pharmacy enterprises optimizing access by patients to the care of pharmacists. We must educate the public about the value of the knowledge and counsel of pharmacists to patients and other providers in managing disease and wellness. Evidence demonstrates that pharmacists focusing on the medication use process can reduce hospital readmissions, exacerbations of chronic disease, adverse drug events and improve patient care outcomes. As an organization, we must provide the leadership to fulfill the promise of our profession. Pharmacy has a powerful story to tell. We must create demand for pharmacists' services by telling our story in order to gain the recognition we deserve.

CHAIR, HOUSE OF DELEGATES (continued)

JAMES A. TROVATO, Pharm.D., M.B.A., BCOP, FASHP (410-706-2751; jtrovato@rx.umaryland.edu) is associate professor and oncology specialist at the University of Maryland School of Pharmacy in Baltimore. Trovato completed a B.S. in pharmacy from the Massachusetts College of Pharmacy, Pharm.D. degree from Purdue University, and an ASHP-accredited oncology residency at the University of Texas Health Science Center at San Antonio. Dr. Trovato is a leader in oncology pharmacy practice, professional education, and residency training. He has developed an innovative collaborative oral chemotherapy management service in the outpatient oncology clinic at the Baltimore VA Maryland Health Care System. He is past-president of the Maryland Society of Health-System Pharmacists. Trovato has served ASHP as Chair, House of Delegates; Chair and Director-at-Large, Executive Committee of the Section of Clinical Specialists and Scientists; Chair, Council on Educational Affairs, multi-year ASHP Delegate, Faculty Liaison, and advisor to the ASHP student chapter.

Dr. Trovato's statement:

Eric Hoffer, an American writer, once stated that "The only way to predict the future is to have the power to shape it". One way of shaping the future of health-system pharmacy practice is through the process of developing professional policies of ASHP. As members of ASHP we can use these policies to help advance our profession and promote the role of the pharmacist in providing patient care.

Priorities for ASHP and its members that I feel are important to shaping the future of our profession include:

- *Development of pharmacy practice models that include preventive care, accountability for patient health outcomes, and reimbursement for cognitive-based services.*
- *Use of technology and informatics to enhance the medication use process and patient safety.*
- *Increase the quality and number of post graduate training opportunities for pharmacists.*
- *Use of board certification for quality assessment and verification of pharmacist's specialized knowledge and skills.*
- *Develop, train, mentor new pharmacy practitioners to take on leadership positions in health-system pharmacy.*

I am humbled to have received this nomination and would welcome the opportunity to serve the pharmacy profession as an ASHP board member.



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Policy Recommendations

Council on Pharmacy Practice

- A. Standardization of Oral Liquid Medication Concentrations
- B. Safe Use of Radiopharmaceuticals
- C. Pharmacist's Role on Ethics Committees
- D. Safe Use of Fentanyl Transdermal System Patches
- E. Automatic Stop Orders
- F. International System of Units

Council on Public Policy

- A. Federal and State Regulation of Compounding
- B. 340B Drug Pricing Program Sustainability
- C. State Prescription Drug Monitoring Programs
- D. Approval of Biosimilar Medications
- E. Management of Blood Products and Derivatives

Council on Therapeutics

- A. Access to Oral Contraceptives Through an Intermediate Category of Drug Products
- B. Expedited Pathways for FDA Drug Approval
- C. FDA Oversight of Laboratory-Developed Tests
- D. Ensuring Effectiveness, Safety, and Access to Orphan Drug Products

Council on Education and Workforce Development

- A. Cultural Competency and Cultural Diversity
- B. Credentialing, Privileging, and Competency Assessment
- C. Education About Patient Safety in the Medication-Use Process
- D. ASHP Statement on Continuing Education

Council on Pharmacy Management

- A. Pharmacy Department Interface with Business Partners
- B. Integration of Pharmacy Services in Multifacility Health Systems
- C. Risk Assessment of Health Information Technology
- D. Documentation of Patient-Care Services in the Permanent Health Record
- E. Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient-Assistance Programs
- F. Fostering Pharmacy Leadership

Section of Clinical Specialists and Scientists

ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics

Board of Directors Reports on Councils. ASHP councils met in Bethesda, Maryland, on September 17–18, 2013. Each report has three sections: Policy Recommendations (new policies initiated by the council, approved by the Board of Directors, and subject to ratification by the House of Delegates); Board Actions (Board of Directors consideration of council recommendations that did not result in new policies, and actions by the Board in areas for which it has final authority); and Other Council Activity (additional subjects the council discussed, including issues for which it has begun to develop policy recommendations). The House will consider an additional policy recommendation initiated by the Section of Clinical Specialists and Scientists and approved by the Board of Directors.



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Board of Directors Report on the Council on Pharmacy Practice

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners in hospitals and health systems. 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.

Kelly M. Smith, *Board Liaison*

Council Members

Kristine P. Gullickson, *Chair* (Minnesota)
Nishaminy Kasbekar, *Vice Chair* (Pennsylvania)
James A. Cattin (Maine)
Julie A. Groppi (Florida)
Margaret A. Huwer (Ohio)
Lindsey R. Kelley (Michigan)
Ashley L. Mains (Colorado)
Lindsey B. Poppe (North Carolina)
Frank G. Saya (California)
Jeffrey R. Scott, *New Practitioner* (Tennessee)
Caroline Small, *Student* (New Mexico)
Tate N. Trujillo (Indiana)
Douglas J. Scheckelhoff, *Secretary*

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C. Pharmacist's Role on Ethics Committees	4
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(Click on title to view section)

Policy Recommendations



A. Standardization of Oral Liquid Medication Concentrations

- 1 To advocate for the development of nationally standardized drug concentrations for
- 2 oral liquid medications; further,

- 3 To encourage hospitals and health systems to standardize concentrations of oral liquid
- 4 medications; further,

- 5 To support the goal of developing standardized doses for pediatric oral liquid
- 6 medications and, when appropriate, for adult doses; further,

- 7 To promote effective instruction of patients and caregivers on how to properly measure
- 8 and administer oral liquid medications.

Rationale

Standardization and simplification are widely accepted methods for reducing variability in processes with risk for error. Many oral liquid medications are available in more than one concentration from manufacturers, and unique pharmacy-compounded formulations also result in a wide variety of concentrations. Standardization at a national level would reduce variability when patients are discharged and have prescriptions filled at pharmacies in the community. Standardization of concentrations within a hospital or health system would reduce the potential for errors in those settings. Standard doses would reduce the potential for error, reduce waste, and improve efficiency. Improved instruction of patients and caregivers would improve proper administration in the home, safely delivering the prescribed dosage of medication.

Background

The Council discussed standardization of concentrations of oral liquid medications in light of a similar policy on intravenous medication concentrations (ASHP policy 1306, [Standardization of Intravenous Drug Concentrations](#)). Although the methods of achieving standardization might be different for intravenous and oral liquid medications, many of the safety implications are similar.

While it is possible to standardize concentrations and doses for most oral liquid medications, many hospitals do not attempt to do so. Those who are successful in standardizing concentrations and doses of oral liquid medications often report reduced workload in addition to reduced errors. Standardization of labels for oral liquid medications was also noted as a means of reducing errors.

Some members described state efforts to standardize concentrations, with the goal of improving transitions of care and patient access upon discharge from the hospital. Some reported cases of patients being discharged, only to return to the hospital because they were discharged on a nonstandard concentration and were unable to have their prescription filled in the community. The development of a national database or compendium of recommended standard concentrations would help avoid the need to repeat the standardization process state by state.

It was noted that movement to bar-coded medication administration is also driving standardization, as is the use of other forms of automation. Efforts to standardize concentrations might also incentivize manufacturers or packagers to produce commercially available dosage forms because the standardization pools volume and makes it economically viable to do so.

The Council discussed the problems of cutting tablets in half or quarters to achieve a smaller dose. Accuracy of splitting is poor, and tablets with special coating or extended-release properties might inadvertently be split. They believed, however, that these issues are different from those surrounding oral liquid medications.



B. Safe Use of Radiopharmaceuticals

- 1 To affirm that radiopharmaceuticals require the same standards for safe procurement,
- 2 handling, preparation, dispensing, administration, monitoring, disposal, and formulary
- 3 consideration as other medications; further,
- 4 To advocate that pharmacy departments, in cooperation with departments of nuclear
- 5 medicine and radiology, provide oversight of radiopharmaceuticals to assure safe use.

Rationale

Many hospitals utilize radiopharmaceuticals for diagnostic imaging tests or for treatment. Most hospitals outsource the preparation of injectable and oral radiopharmaceuticals to external suppliers. Because of the unique nature of these drugs and their narrow scope of use, the pharmacy department is often not involved with their acquisition, handling, or disposal. Reports of improper handling, storage, and disposal suggest that these products should have similar oversight as other drug products used in hospitals.

Background

The Council discussed examples of how patients were harmed because the processes used to manage radiopharmaceuticals were not appropriate. One example included improper batch preparation from a single vial, not meeting best practices for immediate use defined by *United*

States Pharmacopeia (USP) Chapter 797. Another case involved patient exposure to hepatitis C when a contaminated syringe was used to dilute a compound before injection. Last-minute or unscheduled procedures are often problematic, especially when the hospital uses an external supplier for radiopharmaceuticals.

Some new radiopharmaceutical products contain Schedule II controlled substances, necessitating pharmacy involvement for ordering, control, and disposal. Oversight becomes even more problematic when the controlled substance is delivered to the nuclear medicine or radiology department and is never really under the control of the pharmacy.

Most colleges of pharmacy do not teach the principles of radiopharmacy as part of their required curriculum, so many pharmacists are not knowledgeable on proper handling of radioisotopes.

The role of pharmacy and therapeutics (P&T) committees in reviewing and approving radiopharmaceuticals, as they do with other drugs, was discussed. It appears that a growing number of hospitals conduct a formal review of these products, but there is wide variability. Many cited a lack of appropriate policies and procedures on how radiopharmaceuticals should be handled. Many radiopharmaceutical products are also not FDA-approved entities.

One challenge cited as a frequent problem unique to these products is dosing. In some cases, doses may be increased arbitrarily to shorten the time needed for the diagnostic scan, unnecessarily increasing exposure to the patient. In other cases, the dose is expressed as a range, and the actual amount administered is determined by the technician at the time of the scan. Some Council members noted that it is not unusual for radiopharmaceuticals to be administered before the actual physician order is written.

The Council concluded and the Board agreed that pharmacy departments should play a bigger role in assuring safe use of these products. They also concluded that the process used within the facility to ensure the proper use of radiopharmaceuticals was their primary concern, not the outsourcing of the products. The Council also recommended the development of a guidance document on the topic.



C. Pharmacist's Role on Ethics Committees

- 1 To advocate that pharmacists should be included as members of hospital and health-
- 2 system ethics committees and be involved in ethics consultations when appropriate.

Rationale

Many hospitals have a committee or other process by which they consider ethical decisions related to patient care. Many issues that face these committees involve medications, yet often pharmacists do not serve on the committee or are not directly involved in the decision-making process. The number of ethical issues involving medications is expected to increase, given many

new and unique drug products coming into the market. Pharmacist involvement would better inform these committees and consultations.

Background

The Council discussed some contemporary examples of medication-related dilemmas being addressed by ethics committees. One included who should receive a drug product in short supply when there is not enough for all patients who need it. Another example was whether a medication should be used past its expiration date when there is a shortage and no other drug product available. Multidisciplinary teams and committee are known to get better results, strengthening the rationale for pharmacist involvement. The Council and Board also agreed that pharmacists should be included in ethics consultations or similar bedside meetings involving ethical decisions.

Pharmacists should be trained to recognize when to reach out to ethics committee for advice. The need for bioethics training in the pharmacy curriculum and as part of residency training was also discussed. The Council recommended that ASHP offer training to help support pharmacists serving in these roles.



D. Safe Use of Fentanyl Transdermal System Patches

- 1 To advocate for enhanced consumer education and product safety requirements for
- 2 fentanyl transdermal system patches; further,
- 3 To encourage manufacturers of fentanyl transdermal system patches to collaborate
- 4 with pharmacists and other stakeholders to identify and implement packaging, labeling,
- 5 and formulation changes that prevent accidental exposure and facilitate safe disposal.

Rationale

There have been many reports of errors, abuse, and misuse of the fentanyl patch, and while approaches to improving the safe use of the product have been considered, few have been implemented and fatalities related to this product continue. Better consumer education, specific to this unique dosage form, is an important activity, but is often overlooked. Manufacturers could also take additional steps to prevent misuse of the product, through changes to the formulation or to packaging. Pharmacists are in a unique position to help improve the safe use of fentanyl patches.

Background

The Council discussed the numerous reported errors and deaths related to fentanyl patches. Despite raised awareness and various interventions, incidents continue to occur.

The Council reviewed ASHP policy 1106, Pain Management, which reads:

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To encourage the education of pharmacists, pharmacy students, and other health care providers regarding the principles of pain management and methods to minimize drug diversion.

Some of the problems with the patches that have resulted in patient harm include aggressive dosing, not leaving the patch on the skin long enough, and large quantities of drug remaining in used patches, resulting in fatalities when accidentally ingested.

The Council discussed the pros and cons of recommendations from the Institute for Safe Medication Practices (ISMP) and others that a Risk Evaluation and Mitigation Strategy (REMS) be developed for fentanyl patches. One downside of a REMS might be that it could result in reduced access for patients with significant pain. The same would be true if other long-acting opioids required a REMS.

It was suggested that reformulating the product to make it less prone to errors or misuse might help. An example would be making sure the fentanyl had a bitter taste, which would deter infants from putting used patches in their mouths. Another suggestion was to include a disposal container as part of the packaging; when the user is finished with a patch, it could immediately be put into a container, sealed so that it could not be reopened, and then safely discarded.

The Council suggested that ASHP ask providers of patient medication instruction resources to include more information on safe handling and disposal of fentanyl patches, so that the information will be included when care providers print out discharge instructions for patients. The Council also discussed whether ASHP should advocate for these additional education and safety requirements for all transdermal systems or just for those containing fentanyl.



E. Automatic Stop Orders

- 1 To affirm that automatic stop orders are a potential source of medication errors and
- 2 patient harm; further,

- 3 To advocate that the Centers for Medicare & Medicaid Services (1) revise the
- 4 requirement in the Hospital Conditions of Participation that all medication orders
- 5 automatically stop after an arbitrarily assigned period to include other options to
- 6 protect patients from indefinite, open-ended medication orders, and (2) revise the
- 7 remainder of the medication management regulations and interpretive guidelines to be
- 8 consistent with this practice; further,

- 9 To encourage pharmacists to participate in interprofessional efforts to establish
- 10 standardized methods to assure appropriate duration of therapy.

(Note: This policy would supersede ASHP policy 0904.)

Rationale

Automatic stop orders on medications are intended to safeguard patients against unnecessary or prolonged drug therapy, yet they also have been shown to cause medication errors when critical therapy is inadvertently and arbitrarily discontinued. The Centers for Medicare & Medicaid Services conditions of participation (CMS COP) continue to require automatic stop orders, not accounting for shorter lengths of stay and other means of reviewing drug therapy for appropriateness. The CMS COP should be revised to reflect better, more effective approaches to re-evaluating appropriateness of medications.

Background

As part of sunset review, the Council recommended that ASHP policy 0904 be amended as follows (underline indicates new text):

To affirm that automatic stop orders are a potential source of medication errors and patient harm; further,

To advocate that the Centers for Medicare & Medicaid Services (1) revise the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice; further,

To encourage pharmacists to participate in interprofessional efforts to establish standardized methods to assure appropriate duration of therapy.

The Council believed that automatic stop orders still pose a problem and result in preventable medication errors. The policy was revised to restate the purpose of opposing automatic stop orders and to suggest that other mechanisms to prevent prolonged, unnecessary therapy could be adopted, such as pharmacist order reviews, as an alternative to automatic stop orders without the risk of inadvertent medication errors.



F. International System of Units

To discontinue ASHP policy 8612, which reads:

- 1 To not advocate, at this time, adoption of the International System of Units (SI units) as
- 2 the exclusive labeling for drug dosages and concentrations; further,
- 3 To urge labelers to include: (1) units of mass, volume, or percentage concentrations and
- 4 (2) moles or millimoles in labeling until the health professions and the public can be
- 5 educated and be comfortable with use of SI units in prescribing and labeling drug
- 6 products.

Background

As part of sunset review, the Council reviewed policy 8612. The policy was approved in 1986 when there was a push by many, including the American Medical Association, to adopt the International System of Units, which would have resulted in drug dosages and concentrations being expressed in molar quantities rather than units of mass or volume or percent concentration. ASHP believed that such a system would cause much confusion and result in medication errors and therefore adopted policy 8612. Since there has not been a proposal for consideration of SI units in many years, the Council concluded and the Board agreed that the policy is no longer relevant and should be discontinued.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing ASHP policies, 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's Role in Providing Care for an Aging Population](#) (0902)
- [Pharmaceutical Waste](#) (0903)
- [Pharmaceutical Counterfeiting](#) (0401)
- [Ready-to-Use Packaging for All Settings](#) (0402)
- [ASHP Position on Assisted Suicide](#) (9915)
- [Telepharmacy](#) (9920)
- [Pharmacist Validation of Information Related to Medications](#) (9921)
- [Medication Misadventures](#) (9805)
- [Role of Pharmacists and Business Leaders in Health Care Services and Policies](#) (9819)
- [Use of Color to Identify Drug Products](#) (9608)
- [Therapeutic Interchange](#) (8708)
- [Use of Drugs in Capital Punishment](#) (8410)
- [ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control](#)
- [ASHP Statement on the Health-System Pharmacist's Role in National Health Care Quality Initiatives](#)
- [ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness](#)
- [ASHP Statement on Pharmacist Decision-Making on Assisted Suicide](#)
- [ASHP Statement on the Pharmacist's Role in Clinical Pharmacokinetic Monitoring](#)
- [ASHP Guidelines on the Pharmacist's Role in Immunization](#)

Other Council Activity

Pharmacist Scope of Practice

The Council discussed the expanding scope of practice for pharmacists, and the need for and benefit from pharmacist patient-care services is likely to drive additional expansion. State pharmacy practice acts vary greatly in defining or describing the scope of pharmacist patient-care services. Defining a contemporary scope of practice, with guidance on privileging and credentialing, would help individual organizations as they consider pharmacist practice within their settings, and could assist state boards of pharmacy as they consider pharmacist practice regulations within their state, complementing National Association of Boards of Pharmacy (NABP) model practice act language. The Council on Public Policy also discussed a model scope of practice for pharmacists, with a focus on how it could be used with state boards, and

collaborated with the Council on Pharmacy Practice to recommend that ASHP develop a model scope of practice for pharmacists.

The Council discussed the current variability in practice and noted there is a lack of uniformity in what pharmacists are authorized to do for patients at the state level. Access to patient care services of pharmacists is limited in many cases because of what pharmacists are authorized to do, even though demand for services is expected to grow.

The Pharmacy Practice Model Initiative resulted in many recommendations regarding additional pharmacist patient-care services that should be provided, including pharmacist prescribing. These recommendations might serve as a good starting point for the development of a scope of practice document. There was agreement that these roles must also be tied to a privileging and credentialing process, however.

There was recognition that even though a broader scope of practice is needed, there will continue to be more traditional roles and that there will be many pharmacists who wish to remain in those roles. The value of having a special designation, such as “advanced practice pharmacist,” was discussed. The Council noted that while collaborative practice has been a positive step towards expanding pharmacist roles, there needs to be a more advanced scope of practice that also gives the pharmacist responsibility and accountability. The downside and limitations of protocol-driven practice was also discussed.

Repackaging of Oral Dosage Forms

The Council discussed how oral medications are repackaged by hospitals or by third-party repackagers. Quality control varies greatly in both hospital-based and third-party repackaging, and poor systems have resulted in errors and patient harm. The Council reviewed that [*ASHP Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages*](#). They found it to be relevant but in need of revision. The primary focus of the document on hospital repackaging was also cited as additional justification for revision.

The Council discussed different types of repackaging, as defined by USP and FDA, and how the type of packaging determines expiration dating. The Council believed that ASHP providing guidance to hospitals on minimum standards for repackagers could help prevent patient harm by assuring use of high-quality, standards-driven processes.

Procedures used by hospitals in assigning expiration dates are sometimes driven by evidence in the literature, but at other times are more arbitrary. The use of technology in repackaging was also discussed, with concerns over proper use and consideration to how disposable tubing is used and how equipment is cleaned. The need for much more specific guidance was reaffirmed.

The Council concluded that whether hospitals choose to perform repackaging within the pharmacy or outsource the process to a repackager, guidance is needed. The new guidelines should revise the existing technical assistance bulletin, focusing primarily on the hospital but also providing guidance on how to evaluate and choose a repackager.

The Council recommended that the [*ASHP Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages*](#) should be revised.

ASHP Guidelines on Pharmaceutical Services in Correctional Facilities

As part of sunset review, the Council reviewed the [ASHP Guidelines on Pharmaceutical Services in Correctional Facilities](#). They concluded that although the document was generally accurate, many specific terms were outdated and limited the usefulness of the documents. Because of these shortcomings, the Council recommended that it be revised and updated.

ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records

As part of sunset review, the Council reviewed the [ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records](#). They believed that guidelines on the topic serve an important purpose and are needed but that the current document is dated and needs to be revised.

Safe Use of Radiopharmaceuticals

The Council discussed the use of radiopharmaceuticals, which in most U.S. hospitals are typically acquired from an external source. Because of the unique nature of these drugs and their narrow scope of use, the pharmacy department is often not involved with their acquisition, handling, or disposal. Reports of improper handling, storage, and disposal suggest that these products should have similar oversight as other drug products used in hospitals.

Most colleges of pharmacy do not teach the principles of radiopharmacy as part of their required curriculum, so many pharmacists are not well-informed on how to properly handle radioisotopes. Because of the limited knowledge of many pharmacists, and because of the reports of problems, the Council concluded that a guidance document that would assist pharmacy leaders in assuring proper use, storage, and disposal would be desirable.

Insourcing of Sterile Compounding Services

Because of increasing safety concerns following the New England Compounding Center case and the uncertainty of supply created by that case and pending legislation, many pharmacies are considering whether to resume compounding of sterile preparations that had previously been outsourced. The Council discussed whether pharmacies have the knowledge and expertise to safely compound many of these preparations.

Some Council members described the dilemma their institutions are going through as they face these issues. Some are fortunate to have highly knowledgeable sterile compounding supervisors, but personnel with this expertise and advanced knowledge are often not available. It was suggested that ASHP should develop high-level training programs to help develop these sterile compounding specialists. There are too few with this level of knowledge, and many are planning to retire with no one to replace them.

The Council discussed the [ASHP Guidelines on Outsourcing Sterile Compounding Services](#) and [ASHP Guidelines on Compounding Sterile Preparations](#). They found these to documents to be highly relevant and useful when pharmacy departments are considering whether to outsource a product or make it in house.

The Council discussed the preparation-specific issues that often influence decisions on sourcing. In some cases, even though a preparation could be compounded in house, it is outsourced to obtain longer expiration dating. Others noted the unique challenges these preparations bring to small hospitals with limited resources and equipment. The ability to test products for sterility helps, but the reliability of testing laboratories has also come into question and the amount of time required for tests is often impractical.

The ASHP Foundation [Outsourcing Sterile Products Preparation Contractor Assessment Tool](#) was discussed, with Council members noting great value in the tool. Most noted that even if they made a site visit to a compounding pharmacy they would not feel qualified to determine whether the pharmacy was meeting a quality standard.

Organizational Decision Related to Compounded and Specialty Preparations

The Council discussed how decisions are made regarding the sourcing of compounded and specialty preparations. Many pharmacy departments turn to compounding pharmacies to obtain sterile compounded preparations, but processes for determining which products to purchase and how to evaluate compounding pharmacies vary widely. Some hospitals bring preparations to be outsourced to their P&T committee for approval. Others have criteria for evaluating outsourcing contractors.

The Council reviewed existing policy, notably the [ASHP Guidelines on Outsourcing Sterile Compounding Services](#), the [ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System](#), and the [ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System](#). The Council believed that these documents provided the organizational guidance for decisions related to compounded preparations.

The Council discussed results from a survey recently conducted by ASHP on sterile compounding. The results showed that 11% of pharmacies use sterile testing to determine beyond-use dating, 7% compound from nonsterile ingredients, and a majority use outsourced compounding pharmacies. Of those surveyed, 43% use the P&T committee to make decisions to decide on compounding pharmacies.

The Council reviewed ASHP policy 0616, [Safe and Effective Extemporaneous Compounding](#), and ASHP policy 0617, [Accreditation of Compounding Facilities](#), and found both of these policies to still be relevant.

The Council concluded that organizations should have a policy on how to evaluate external compounding pharmacies but stopped short of saying vendors must be approved by the P&T committee. They believed that the drug should be approved by the committee, but seeking committee approval of the source was not practical and would likely not add value. It was also noted that the Joint Commission does require approval of contracts for outside suppliers providing products or services to patients.



The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

Board of Directors Report on the Council on Public Policy

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice in hospitals and health systems. 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.

Steven S. Rough, *Board Liaison*

Council Members

Kristina L. Butler, *Chair* (Oregon)
John B. Hertig, *Vice Chair* (Indiana)
Joe R. Anderson (New Mexico)
Leigh A. Briscoe-Dwyer (New York)
Andrea K. Darr (South Dakota)
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Cara Milburn, *Student* (West Virginia)
Stephen R. Novak (North Carolina)
John D. Pastor III (Minnesota)
Elizabeth C. Perry, *New Practitioner* (Louisiana)
Sarah J. Steinhardt (Florida)
Brian M. Meyer, *Secretary*

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Policy Recommendations



A. Federal and State Regulation of Compounding

- 1 To advocate that the applicable compendial standards of the United States
- 2 Pharmacopeia be included in state and federal laws and regulations that govern
- 3 compounding by any health professional; further,

- 4 To advocate for state registration of compounding facilities (e.g., pharmacies, physician
- 5 offices, clinics, ambulatory surgery centers) that provide products for specific patient
- 6 prescriptions or in anticipation of specific patient prescriptions or medication orders;
- 7 further,

- 8 To advocate for Food and Drug Administration registration and current good
- 9 manufacturing practices requirements for outsourcing facilities that compound and sell
- 10 products without patient-specific prescriptions across state lines; further,

- 11 To advocate that registration of compounding facilities at either the federal or state
- 12 level include registration fees that are used to improve patient safety and care by
- 13 educating state and federal inspectors, improving the frequency and effectiveness of
- 14 compliance inspections, and enhancing interagency communications; further,

- 15 To advocate that state and federal agencies develop standardized definitions and
- 16 nomenclature relating to sterile and nonsterile compounding, including but not limited
- 17 to definitions of compounding, manufacturing, repackaging, and relabeling.

(Note: This policy would supersede ASHP policy 1308.)

Rationale

The practice of compounding has evolved along with the profession of pharmacy. With the advancement of pharmaceutical manufacturing, the preparation of individualized medications based on a prescription or medication order has also evolved. In particular, sterile preparation and related best practices (e.g., ASHP guidelines) and standards of practice (relevant USP chapters) have also evolved. However, cases of contamination, adulteration, and misbranding have persisted, culminating in the meningitis tragedy caused by contaminated sterile preparations compounded by the New England Compounding Center (NECC). That contamination resulted in 64 deaths and over 700 patient cases, as reported by the Centers for Disease Control and Prevention.

The NECC case highlighted the need for accountability and clear regulatory jurisdiction between state boards of pharmacy and the federal Food and Drug Administration. Since 1997,

there has been discussion and debate over the proper oversight of compounding. The NECC case demonstrated the real and potential national public health threat posed by the lack of oversight of the practice of compounding. This threat is particularly acute when high-risk sterile products are prepared in large quantities and sold across state lines without adherence to either relevant USP chapters or Food and Drug Administration (FDA) current good manufacturing practices (cGMPs). Over the past 16 years, a series of court decisions in various federal circuits has resulted in a patchwork application of Section 503A of the Federal Food Drug and Cosmetic Act. In addition, a new type of supplier of sterile compounded preparations has emerged to fill a critical need for high-risk sterile preparations for hospitals and health systems. Those health systems are often unable to make the capital and/or human resource investments to prepare these high-risk preparations and seek to use outside suppliers to meet their patients' needs. After the Council met in September 2013, Congress passed H.R. 3204, the Drug Quality and Security Act (DQSA) and President Obama signed it into law (P.L. 113-54) on November 27, 2013. Prior to the passage of the DQSA, these outside suppliers operated as licensed pharmacies and in some cases also registered as drug establishments with the FDA. However, the authority for FDA to inspect and enforce either cGMPs or USP standards was unclear. DQSA is designed to provide that clarity as well as delineate the accountability between the FDA and state boards.

The proposed policy recommendation is intended to advocate for federal oversight of certain entities that compound and engage in interstate commerce. This aspect was added to address the wider public health threat when these preparations can potentially be distributed nationwide. The proposed recommendation would also continue current ASHP policy calling for state regulation of compounding by health professionals (including pharmacists, physicians, and nurses) that would require meeting the applicable USP standards. The policy further addresses the need for federally registered compounding facilities to meet applicable cGMPs and state-registered facilities engaged in "traditional compounding" (i.e., compounding for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders) to meet applicable USP standards. The policy also advocates for adequate funding through user fees from these facilities to ensure adequate resources for training and inspection by the relevant regulatory body. Finally, the policy calls for standard definitions and nomenclature for certain terms that may have different definitions within federal law and regulation and between federal and state law and regulation (FDA, Drug Enforcement Administration [DEA], pharmacy practice act and regulation).

Background

The Council voted and the Board agreed to recommend amending policy 1308 as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To advocate ~~that for state laws and regulations that govern compounding by health professional include~~ the applicable compendial standards of the United States Pharmacopeia be included in state and federal laws and regulations that govern compounding by any health professional; further,

To advocate for state registration of compounding facilities (e.g., pharmacies, physician offices, clinics, ambulatory surgery centers) that provide products for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders; further,

To advocate for Food and Drug Administration registration and current good manufacturing practices requirements for outsourcing facilities that compound and sell products without patient-specific prescriptions across state lines; further,

To advocate that registration of compounding facilities at either the federal or state level include registration fees that are used to improve patient safety and care by educating state and federal inspectors, improving the frequency and effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate that state and federal agencies develop standardized definitions and nomenclature relating to sterile and nonsterile compounding, including but not limited to definitions of compounding, manufacturing, repackaging, and relabeling.

The Council and Board substantially revised policy 1308 and added clauses to reflect the need for policy to address additional contemporary and emerging issues related to compounding and the public policy proposals designed to address them.

The Council and Board reviewed ASHP's policies on compounding in general and those that deal with federal and state regulation in particular. In light of the meningitis outbreak in late 2012, and subsequent congressional review of FDA and state board oversight, the Council and Board considered addressing the role of FDA with respect to the preparation and distribution of compounded preparations, particularly when entered into interstate commerce. The Council and Board revised policy 1308 and added additional clauses. In revising policy 1308, the Council was guided by existing compounding policies, particularly policy 0616, which describes extemporaneous compounding, the need for adequate training, and the role of USP standards applicable to compounding.

The Council also reviewed policy 0617, [Accreditation of Compounding Facilities](#). It underscored that this policy encouraged unaccredited facilities to seek accreditation when engaged in extemporaneous compounding. It concluded that the policy is adequate, since many hospital and health systems are currently accredited. It further noted that the term "nationally credible" accreditation body needs to be defined.



B. 340B Drug Pricing Program Sustainability

- 1 To affirm the intent of the federal drug pricing program (the “340B program”) to stretch
- 2 scarce federal resources as far as possible, reaching more eligible patients and
- 3 providing more comprehensive services; further,

- 4 To advocate legislation or regulation that would expand eligibility for the 340B program
- 5 in accordance with Health Resources and Services Administration oversight and the
- 6 intent of the program; further,

- 7 To advocate for clarification and simplification of the 340B program and any future
- 8 federal discount drug pricing programs with respect to program definitions, eligibility,
- 9 and compliance measures to ensure the integrity of the program; further,

- 10 To encourage pharmacy leaders to provide appropriate stewardship of the 340B
- 11 program by documenting the expanded services and access created by the program;
- 12 further,

- 13 To educate pharmacy leaders and health-system administrators about the internal
- 14 partnerships and accountabilities and the patient-care benefits of program
- 15 participation; further,

- 16 To educate health-system administrators about the information technology and other
- 17 resources required to support 340B program compliance and documentation; further,

- 18 To encourage communication and education concerning expanded services and access
- 19 provided by 340B participants to patients in fulfillment of its mission.

(Note: This policy would supersede ASHP policy 0506.)

Rationale

Statutory and other policy changes to the federal drug pricing (“340B”) program in recent years have spurred an increase in the number of hospitals and other eligible entities that participate. Over the past two years, the number of 340B-eligible and participating hospitals has more than doubled. Policymakers and other stakeholders have raised questions about the integrity of the program as well as its original intent. In addition, compliance with the current program continues to be challenging. Specifically, clarification to existing policy guidance or via newly proposed regulation is needed with respect to various issues. These include the definition of a patient, use of contract pharmacies, eligibility by various hospitals, use of group purchasing organizations to purchase drugs for inpatient and outpatient use.

Moreover, expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) will allow additional hospitals to participate in the program and continue the scrutiny and questions from policymakers and stakeholders. These factors demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment. (See additional discussion of these factors in the minutes of the Council on Pharmacy Management.) In light of these contemporary issues, policy 0506 was revised by the Council after extensive consultation and collaboration with the Council on Pharmacy Management.

The original intent of the 340B program was to “to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (H.R. Rept. 102-384, pt. 2, at 12 [1992]). Policy 0506 was revised to continue to reflect the need for expansion of the program in alignment with its intent. This may or may not include use in the inpatient setting. Other revisions to the policy are designed to stress the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. In response to policymaker and stakeholder concerns, the revised policy seeks to highlight the important intent and role of the 340B program and stress the need for its continued sustainability.

Background

The Council voted and the Board agreed to recommend amending policy 0506 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To affirm the intent of the federal drug pricing program (the “340B program”) to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would expand eligibility for ~~federal discount drug-pricing programs (e.g., the 340B program) to inpatient drugs for disproportionate share hospitals;~~ in accordance with Health Resources and Services Administration oversight and the intent of the program; further,

~~To advocate administrative simplification of existing and any future federal discount drug-pricing programs with respect to qualification and implementation.~~

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators about the information technology and other

resources required to support 340B program compliance and documentation; further,

To encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

The Council reviewed current policies 0506 and 1219 relating to the 340B program in the context of various communications from members of Congress as well as reports and analyses from stakeholder organizations. The Council and Board noted the attention the program continues to receive from various policymakers and stakeholders but also the new audit and other authority granted to the Health Resources and Services Administration to maintain program integrity. In response to this new attention and emphasis on program integrity, the Council, with input from the Council on Pharmacy Management, revised policy 0506, and the Board concurred.



C. State Prescription Drug Monitoring Programs

- 1 To advocate for uniform state prescription drug monitoring programs that collect
- 2 timely, relevant, and standard information about controlled substances prescriptions;
- 3 further,

- 4 To advocate that the design of these programs should balance the need for appropriate
- 5 therapeutic management with safeguards against fraud, misuse, abuse, and diversion;
- 6 further,

- 7 To advocate that such programs be structured as part of electronic health records and
- 8 exchanges to allow prescribers, pharmacists, and other practitioners to proactively
- 9 monitor data for appropriate assessment; further,

- 10 To advocate for interstate integration to allow for access by prescribers, pharmacists,
- 11 and other practitioners across state lines; further,

- 12 To advocate for federal and state funding to establish and administer these programs;
- 13 further,

- 14 To promote research, education, and implementation of best practices in prescription
- 15 drug monitoring programs.

(Note: This policy would supersede ASHP policy 1122.)

Rationale

Recent programs initiated by chain pharmacies in response to compliance agreements with DEA and other regulatory bodies regarding the dispensing of controlled substances prompted a review

of ASHP policy 1122. In addition, policy statements by medical organizations concerning these compliance agreements were discussed. These actions relate to the growing concern by policymakers about the abuse of prescription drugs and actions to remedy it. Policy 1122 was revised to describe the need for timely and relevant information about controlled substances prescriptions available through state prescription drug monitoring programs (PDMPs). Some PDMPs do not update information in real time; updating may even lag reporting by days or weeks. This weakness allows opportunity for abuse. Moreover, relevant information is sometimes not required, which impacts the ability of practitioners to make relevant clinical decisions. Further, PDMPs need to be fully integrated across state lines so information from other jurisdictions is available to prevent abuse and misuse. Finally, the policy was revised to include the need for research, education, and implementation of best practices in PDMPs. Such research and education would serve to raise awareness about how to best address the growing public health issue of prescription drug abuse and misuse.

Background

The Council voted and the Board agreed to recommend amending policy 1122 as follows (underscore indicates new text):

To advocate for uniform state prescription drug monitoring programs that collect timely, relevant, and standard information about controlled substances prescriptions; further,

To advocate that the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further,

To advocate that such programs be structured as part of electronic health records and exchanges to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment; further,

To advocate for interstate integration to allow for access by prescribers, pharmacists, and other practitioners across state lines; further,

To advocate for federal and state funding to establish and administer these programs; further,

To promote research, education, and implementation of best practices in prescription drug monitoring programs.

The Council revised policy 1122 as part of a review of the issue of prescription drug abuse, corporate pharmacy compliance programs, medical association statements and the function that prescription drug monitoring programs can serve in addressing this public health issue. The Board concurred in these revisions.



D. Approval of Biosimilar Medications

- 1 To encourage the development of safe and effective biosimilar medications in order to
- 2 make such medications more affordable and accessible; further,

- 3 To encourage research on the safety, effectiveness, and interchangeability of biosimilar
- 4 medications; further,

- 5 To support legislation and regulation to allow Food and Drug Administration (FDA)
- 6 approval of biosimilar medications; further,

- 7 To support legislation and regulation to allow FDA approval of biosimilar medications
- 8 that are also determined by the FDA to be interchangeable and therefore may be
- 9 substituted for the reference product without the intervention of the prescriber;
- 10 further,

- 11 To oppose the implementation of any state laws regarding biosimilar interchangeability
- 12 prior to finalization of FDA guidance; further,

- 13 To require postmarketing surveillance for all biosimilar medications to ensure their
- 14 continued safety, effectiveness, purity, quality, identity, and strength; further,

- 15 To advocate for adequate reimbursement for biosimilar medications that are deemed
- 16 interchangeable; further,

- 17 To promote and develop ASHP-directed education of pharmacists about biosimilar
- 18 medications and their appropriate use within hospitals and health systems; further,

- 19 To advocate and encourage pharmacist evaluation and the application of the formulary
- 20 system before biosimilar medications are used in hospitals and health systems.

(Note: This policy would supersede ASHP policy 1218.)

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. Although the FDA has not yet approved any medications as biosimilars, as of early September 2013, it had received 57 requests for initial meetings to discuss developing biosimilars for 13 different brand-name medications. At the state level, legislation has

been proposed and enacted requiring patient and/or prescriber notification that a biosimilar medication has been interchanged. It is important to note that pharmacists cannot substitute a biosimilar medication unless the FDA has deemed that biosimilar to be interchangeable.

In 2013, proposals in five states (Florida, North Dakota, Oregon, Utah, and Virginia) have become law. Legislation has failed to pass in eleven states (Arizona, Arkansas, California, Colorado, Delaware, Illinois, Indiana, Maryland, Mississippi, Texas, and Washington).

In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, in 2013, a Pennsylvania a House bill would require the person presenting a prescription to consent in writing to the substitution, the pharmacist to notify the prescriber in writing within 72 hours of dispensing the medication, and the pharmacy and prescriber to keep a written record of the substitution for at least 5 years. Current state law on generic substitution requires the pharmacist to notify the purchaser but does not require written consent of the purchaser. Physicians note on the prescription via the “dispense as written” code whether the patient must receive the brand-name medication or if it is permissible to dispense a generic instead.

Revisions to policy 1218 are needed to have a clear position on state legislation and regulation concerning the interchangeability of biosimilars. This is particularly important since the FDA has not finalized its guidance on interchangeability.

Background

The Council voted and the Board agreed to recommend amending policy 1218 as follows (underscore indicates new text):

To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,

To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,

To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; further,

To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

The Council reviewed existing policy 1218 in light of current state legislative activity to enact prescriber and patient notification requirements. It also noted the activities by proponents and opponents of state legislative proposals as well as requests for assistance by state affiliates. Finally, it reviewed a recommendation from the House of Delegates asking ASHP to address the prescriber/patient notification requirements. The Council concluded and the Board agreed that clarifying language was important and revised the policy accordingly.



E. Management of Blood Products and Derivatives

To discontinue ASHP policy 9919, which reads:

- 1 To strongly encourage the computer software industry to provide data fields for lot
- 2 number, expiration date, and other necessary and appropriate information for blood
- 3 products and derivatives and biologicals, in order to facilitate compliance with
- 4 regulatory requirements concerning the use of these products, particularly with respect
- 5 to recalls or withdrawals.

Background

The Council discussed policy 9919 as part of sunset review. The Council and Board considered policy 9919 redundant with ASHP policy 1003, FDA Authority on Recalls, which reads:

To strongly encourage the Food and Drug Administration (FDA) to develop a standard recall notification process and format to be used by all manufacturers to facilitate the timely removal of recalled drugs; further,

To advocate that such notification should (1) come from a single source, (2) clearly identify the recalled product, (3) explain why the product is being recalled, (4) provide a way to report having the recalled product, (5) give instructions on what to do with the recalled product, and (6) be provided concurrently to all entities in the supply chain; further,

To advocate that the FDA be given the authority to order mandatory recalls of medications; further,

To urge the FDA to require drug manufacturers and the computer software industry to

provide bar codes and data fields for lot number, expiration date, and other necessary and appropriate information on all medication packaging, including unit dose, unit-of-use, and injectable drug packaging, in order to facilitate compliance with recalls or withdrawals and to prevent the administration of recalled products to patients; further,

To urge the FDA to encourage postmarketing reporting of adverse events and product quality issues to enhance the recall system.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing ASHP policies, 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.)

- [Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Drug Therapy Management](#) (0905)
- [Pharmaceutical Product and Supply Chain Integrity](#) (0907)
- [Pharmacist Role in the Health Care \(Medical\) Home](#) (0908)
- [Regulation of Interstate Pharmacy Practice](#) (0909)
- [Drug Nomenclature](#) (9011)
- [ASHP Statement on Confidentiality of Patient Health Care Information](#)

Other Council Activity

Controlled Substances Regulation

Council members discussed the increasing use of centralized facilities to provide medications to a variety of inpatient and outpatient settings. Organizations are implementing these facilities in order to effectively use financial resources and maintain patient safety. However, differing interpretations of relevant state and federal laws and regulations with respect to the repackaging and compounding of controlled substances represents a barrier to their full implementation. The Council reviewed existing policies 1311 and 9813 and found them to still be appropriate.

Thus, the Council discussed advocacy options to either the DEA for changes in its regulations or the Congress for changes in the Controlled Substances Act as it relates to central fill by hospitals and health systems as well as repackaging and compounding of controlled substances for use within the health system. These changes are particularly needed for multi-hospital systems that operate across state lines. In these cases, differing interpretation by state boards of pharmacy, state drug control agencies, the FDA, and the DEA can lead to uncertainty about complying with multiple agencies and jurisdictions. After assessment by ASHP, the Council agreed to an ongoing review of advocacy options to determine if additional policy is needed.

Model Scope of Practice

The Council noted that the recommendations of the Pharmacy Practice Model Initiative (PPMI) contained numerous recommendations that were not adequately reflected in the National Association of State Boards of Pharmacy (NABP) Model State Pharmacy Act and Model Rules or most state pharmacy practice acts and regulations. The Council felt that a review of the Model Act and perhaps other representative state practice acts could be conducted to identify those elements that needed to be developed by ASHP and ultimately used by state affiliates in their advocacy before state legislatures and boards of pharmacy to help achieve the PPMI recommendations. The Council also recognized that to be effective other pharmacy stakeholders (including NABP) would need to be engaged. As a first step, the Council voted to identify these provisions and develop a document that would make the case for needed changes. It is envisioned that from such a document, specific model language would be developed. The Council's discussions were coordinated with the Council on Pharmacy Practice, which arrived at a similar conclusion.

Technician Staffing Ratios and Related Issues

The Council reviewed current ASHP policy concerning pharmacy personnel and whether revisions were needed to respond to state legislation that would increase technician-to-pharmacist ratios to potentially unsafe levels. Discussion also included consideration of designated technician task levels, depending on documentation (skills, experience, competency, credentials) that would permit a higher ratio, as well as allowances for a technician to check the work of other technicians (tech-check-tech) and other innovative uses, such as recording medication histories as part of medication reconciliation.

After much discussion regarding the current advocacy at the state level by corporate pharmacy to increase technician-to-pharmacist ratios, the Council noted that the policy discussion needed to be about the correlation between technician competency and an expanded scope of practice for technicians and pharmacists. Council members observed that to achieve many of the PPMI recommendations, effective and efficient use of technicians was imperative. At the same time, Council members recognized that current and additional published research on the safe use of technicians and their optimal use was needed to advocate for increased roles for technicians and achievement of PPMI recommendations.

Distinctive Labeling of Standardized Drug Concentrations and Dosing Units Required by FDA

The Council reviewed the House of Delegates recommendation to advocate for an FDA requirement for distinctive labeling for standardized drug concentrations. The Council concluded that it was premature to advocate to the agency before more data are available. Council members also noted that ASHP policy 1306, [Standardization of Intravenous Drug Concentrations](#), passed this year by the House, represented an initial step, but that more information was needed. Members suggested adding relevant questions on the next annual ASHP survey of hospitals and to continue to monitor the issue.



The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

Board of Directors Report on the Council on Therapeutics

The Council on Therapeutics is concerned with ASHP professional policies related to the safe and appropriate use of medicines. 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.

Larry C. Clark, *Board Liaison*

Council Members

Joel A. Hennenfent, *Chair* (Missouri)
Kersten Weber Tatarelis, *Vice Chair* (Illinois)
Karen Berger, *New Practitioner* (New York)
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(Click on title to view section)

Policy Recommendations



A. Access to Oral Contraceptives Through an Intermediate Category of Drug Products

- 1 To support expanded access to oral contraceptives through an intermediate category of
- 2 drug products that do not require a prescription but are available only from
- 3 pharmacists and licensed health care professionals who are authorized to prescribe
- 4 medications; further,

- 5 To advocate that these products be provided only under conditions that ensure safe
- 6 use, including the availability of counseling to ensure appropriate self-screening and
- 7 product selection; further,

- 8 To advocate that the proposed reclassification of these products be accompanied by
- 9 coverage changes by third-party payers to ensure that patient access is not
- 10 compromised.

Rationale

There have been repeated calls to make oral contraceptive products more widely available, with the intent of expanding access to women's reproductive health therapies and reducing unintended pregnancies. These proposals have merit, but ASHP believes that there are important differences in safety and effectiveness profiles for drug products within this class that necessitate the availability of a pharmacist or other health care professional to provide patient guidance. ASHP supports the availability of these products via an intermediate category of drug products, as described in ASHP policy 0220, [Intermediate Category of Drugs](#), and the [ASHP Statement on Criteria for an Intermediate Category of Drug Products](#), which would facilitate appropriate use of these therapies after patient assessment and professional consultation by a pharmacist or other licensed health care professional who is authorized to prescribe medications. Patient screening and product selection would be improved through pharmacist-provided counseling that assists patients in identifying absolute and relative contraindications (e.g., hypertension, heart or kidney disease) and assessing other patient-specific factors (e.g., adherence practices). This process would guide the determination of whether a progestin-only or combination oral contraceptive product would be more safe and effective for an individual patient. ASHP does not believe that the current model for behind-the-counter access to some drug products (e.g., pseudoephedrine, emergency contraception) is appropriate for oral contraceptives because it would place the pharmacist in a gatekeeping role, not the clinical one that is necessary to ensure safe and effective use of these therapies.

Given the intent to expand access to these therapies, ASHP advocates that the proposed reclassification should not result in increased costs to women. Modifications to national, regional, and local drug coverage decisions may be needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, ASHP believes that the reclassification would result in increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening, product selection, counseling, therapeutic monitoring, and documentation of the care provided in the pharmacy and medical record. Therefore, ASHP advocates that pharmacists should be compensated for these and other patient-care services as described in ASHP policy 1307, [Pharmacist Recognition as a Health Care Provider](#).

Background

The Council considered proposals for nonprescription availability of oral contraceptives in follow-up to a 2011 discussion of this issue. In 2011, the Council considered a [paper](#) authored by the American College of Clinical Pharmacy's Women's Health Practice and Research Network, as well as statements from patient advocacy groups, that called for broader access to these therapies through nonprescription access. At that time, the Council did not oppose or support these proposals, citing concerns over differing effectiveness and safety profiles for progestin-only and combination oral contraceptive products. The Council revisited this issue in light of recent studies that used modeling to evaluate the safety and effectiveness of a theoretical nonprescription model for providing these therapies, as well as the publication of an opinion paper by the American College of Obstetricians and Gynecologists in 2012 that advocates for nonprescription access to these therapies.

The occurrence of unintended pregnancies has remained high despite efforts to provide better education about birth control options. A high percentage of women with unintended pregnancies lack access to appropriate prenatal care, which in turn results in higher rates of low birth weight and other sequelae that have long-term implications for the infant as well as increased costs to the health care system. Other contraceptive options (e.g., condoms, spermicides) are available without a prescription, but these options have significantly lower rates of effectiveness than oral contraceptives. Questions remain as to whether access alone through nonprescription availability of oral contraceptives would decrease unintended pregnancies. Further, studies that have attempted to simulate nonprescription access by studying the access preferences of women in communities in the United States near the Mexican border have found some evidence that women of lower socioeconomic status prefer to obtain these drug products from a health clinic. However, it was noted that this evidence is limited to small pilot studies. Despite limitations in evidence describing the potential impact of the proposed change, the Council and Board believed that broader availability of oral contraceptives would assist in increasing access to contraception, and therefore, supported the intent behind proposals to reclassify these therapies.

The Council considered whether oral contraceptives met established Food and Drug Administration (FDA) criteria for nonprescription status—which include that the benefit of use must outweigh the risk, ability of patients to self-diagnose, provision of adequate labeling, and no need for guidance from a health care professional to ensure proper use. The discussion focused on whether the final criterion could be effectively met. The Council strongly believed that differences in the safety and effectiveness of progestin-only and combination oral contraceptive products would complicate patients' ability to self-select treatment, and the Board concurred. Combination

products have been shown to have increased safety risks. For example, women using drospirenone-containing products have a higher incidence of venous thromboembolism. Drospirenone can also increase potassium levels, which can be problematic for some patients with cardiac and renal disease. Progestin-only products are generally safe for most patients. However, these products can be less effective if patients do not closely adhere to directions for use (e.g., consistent timing of administration). The Council and Board also envisioned a scenario in which not one, but multiple oral contraceptives would be available as nonprescription products. This undesirable situation was likened to the current challenge confronting patients when selecting from an array of nonprescription cough and cold products.

Further, the Council and Board found that while results from studies evaluating patients' ability to self-screen for contraindications and precautions were largely favorable, results were sometimes inconsistent. Hypertension was a commonly overlooked relative contraindication. Counseling is an important mechanism through which pharmacists can identify contraindications and precautions, improve medication adherence, recommend the appropriate action when doses are missed, and relate other information that promotes effective and safe use of these therapies. Studies comparing oral contraceptive use in collaborative practice and other models have demonstrated improved adherence when pharmacist intervention is provided. Finally, the Council and Board noted the need for appropriate documentation of the use of these therapies to support drug interaction screening.

In light of these concerns, the Council strongly believed that these therapies would be best provided under a system described by ASHP policy 0220, [Intermediate Category of Drugs](#), and the [ASHP Statement on Criteria for an Intermediate Category of Drug Products](#). The Board supported this recommendation, which would provide the dual benefit of expanding access while also promoting the safe and effective use of these therapies under the guidance of a pharmacist or authorized prescriber. The Council and Board strongly preferred this approach to the existing behind-the-counter model that has been used for pseudoephedrine and emergency contraception. That model is undesirable because it places the pharmacist in a policing role, rather than a clinical one. The Council and Board recognized that the intermediate category does not yet exist, but were encouraged by outcomes from a March 2012 FDA public meeting to gather stakeholder input on strategies to expand access to drug products. While the specific term "intermediate category" was not used, participants were highly supportive of a model consistent with this terminology, as described in ASHP policy.

In recommending availability of oral contraceptives via an intermediate category of drug products, the Council and Board emphasized that any change to the point of access for these therapies should not increase patient costs. Of note, under changes defined in the Affordable Care Act, most women with health insurance now obtain prescribed oral contraceptives without a co-payment. Policymakers and payers were encouraged to ensure that the transition of oral contraceptives from prescription status to the intermediate category be cost neutral to the women it is intended to benefit. Further, the Council and Board directed ASHP to advocate for a mechanism that would provide compensation to pharmacists who provide these and other clinical services. This perspective is reflected in ASHP's efforts to achieve provider status, as described in ASHP policy 1307, [Pharmacist Recognition as a Health Care Provider](#). Language to this effect was not added to this policy to avoid repetition with existing policy.



B. Expedited Pathways for FDA Drug Approval

- 1 To support the use of expedited pathways for Food and Drug Administration (FDA)
- 2 approval of new drugs that expand access to innovative therapies while protecting
- 3 patient safety; further,

- 4 To advocate for the development of unique labeling requirements that would be used
- 5 on an interim basis to identify products approved by these pathways in order to
- 6 increase awareness of data limitations and guide clinician use of these drugs until
- 7 additional evidence becomes available; further,

- 8 To advocate that the FDA be diligent in enforcing postmarketing commitments for drug
- 9 products approved via expedited pathways, including utilizing its existing authority to
- 10 enforce penalties when these requirements are not met; further,

- 11 To encourage research to evaluate the impact of expedited pathways on drug product
- 12 development and patient care, including drug development timelines and costs, overall
- 13 health care costs, patient access to care, and the effectiveness and safety of these
- 14 therapies.

Rationale

Expedited approval programs provided by the FDA have resulted in substantial public health benefits as illustrated by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. The FDA provides four mechanisms to expedite the development and review process for drugs: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The structure and requirements for each of these mechanisms differs as described in a [2013 draft guidance for industry](#). However, to qualify for any of these programs a drug must (1) address an unmet medical need, (2) provide benefit over available drug treatments, and (3) be used in the treatment of a serious or life-threatening condition. Further, the FDA guidance states that these programs are “intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies’ benefits justify their risks.” Processes used to ensure a favorable risk–benefit profile include, but are not limited to, requirements for postmarketing studies to evaluate safety and effectiveness of the drug as used in real-world scenarios. However, the accelerated approval program is the only program that includes postmarketing studies as a requirement of the program. The FDA has discretion to require additional studies on a case-by-case basis for drug products approved via the other expedited mechanisms. Despite these safeguards, some features of these programs (e.g., smaller clinical trials, alternate trial designs, or limited-duration trials) can result in increased patient risk because less is known about a drug’s side effect profile and efficacy due to

limited patient exposure. In addition, as with all drugs, safety assessments benefit from use of the drug in post-approval patient populations, which better reflect real-world use as compared to the controlled environment of a clinical trial.

Because these drugs represent medical advances, their post-approval use can be extensive. Further, off-label use of these drug products, like all therapies, is common. However, prescribers and other clinicians are frequently unaware that an expedited pathway was utilized and that evidence limitations exist. This scenario raises significant concerns about whether there is sufficient clinician awareness to ensure appropriate use of drugs approved via these pathways. Therefore, ASHP proposes unique labeling requirements that would increase awareness through use of a logo or other mechanism that would be used on an interim basis to inform clinicians about data limitations and provide guidance on appropriate use. This labeling would describe appropriate patient populations and monitoring parameters. Similar labeling requirements have been proposed for a new pathway being considered for the development of antibiotics used to treat life-threatening infections. ASHP supports the approach, but recommends that the increased labeling requirements be discontinued once the drug product manufacturer and FDA agree that sufficient data is available to support safe and effective use, or after the drug manufacturer completes any required postmarketing study commitments.

Given data limitations associated with approval of these therapies, ASHP advocates that the FDA be extremely diligent in ensuring that postmarketing commitments are met. Further, the FDA should use its existing authority as described under 21 CFR 314 subpart H and 21 CFR 601 subpart E if timelines or expectations for these commitments are not satisfactory. This authority allows the FDA to take legal action through penalties that include requiring labeling changes or rescinding marketing approval.

Finally, ASHP believes that there is a need for research to determine whether these expedited pathways are achieving the desired benefits, which include decreasing the time and costs associated with drug product development, lowering overall health care costs, and increasing patient access to safe and effective drug therapies.

Background

The Council considered pathways for expedited FDA approval of drugs, including the new breakthrough therapy designation that was launched in 2012 and a proposed accelerated pathway for antibiotics. The Council and Board supported use of expedited pathways to bring novel therapies to market more quickly. The value of these programs in providing patients more timely access to innovative treatment options was highlighted by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. This approach resulted in an explosion of new therapies, including antiretrovirals, which greatly extended patient survival. Further, the use of expedited pathways with reduced clinical trial requirements is necessary in many situations. For example, manufacturers of therapies used to treat rare conditions and infections would be challenged to identify a sufficient number of patients to meet the enrollment requirements of more extensive clinical trials. Increasing emphasis on pharmacogenomics will also likely result in smaller clinical trials based on the lower prevalence of certain genetic factors.

The Council and Board acknowledged the benefits of expedited pathways, but also expressed concern about the safety and practice implications of these models. It was noted that once a drug is approved, prescribers and other clinicians are generally unaware of any limitations in the evidence used to support FDA approval. The Council viewed this as a significant

shortcoming, stating that knowledge of evidence limitations is an important factor to consider when evaluating the risk versus benefit of using the drug for an individual patient. The Board agreed with this assessment. Further, evidence deficiencies should be considered during the formulary decision-making process, including determining if there is a need for restrictions on use (e.g., required laboratory testing, access restricted to designated prescribers). The Council and Board supported FDA processes intended to ensure patient safety, but noted that the accelerated approval program is the only program that requires postmarketing studies. The FDA uses its discretion on a case-by-case basis to determine whether to require additional studies for drugs approved via other expedited mechanisms.

The Council also viewed favorably a model described for the proposed Limited Population Antibacterial Drug (LPAD) approval pathway, which would facilitate approval of antibiotics used to “treat serious and life-threatening infections for which there are currently few or no satisfactory treatment options.” This model includes a proposal to create unique labeling requirements, including use of a logo to distinguish products approved using this pathway. Other requirements intended to “provide notice to the health care community and payers that these products carry less precise estimates of risk” include a description of the indicated populations and an explanation as to why the product’s use should be limited. While the FDA has not categorized the proposed LPAD pathway as expedited, the Council recognized that it is a similar scenario in which increased awareness among clinicians would improve appropriate drug use. The Council appreciated the enhanced labeling requirements for the proposed pathway and recommended that a similar approach be used for the expedited pathways. The Board supported this approach. The intent of these labeling requirements is not to discourage drug use, but rather to inform appropriate use. Further, the logo and labeling requirements would be removed once the manufacturer has met the postmarketing commitments or other milestones agreed upon by the FDA and manufacturer. The Council and Board believed such a model would continue to encourage innovation by drug manufacturers and protect patients without the need for more formal restrictions, such as REMS, which have been criticized as an attempt to regulate the practice of medicine.

The importance of pharmacovigilance efforts was highlighted, including the critical need to ensure that postmarketing commitments required by the FDA are completed in a timely fashion. While the overall rate at which these commitments are fulfilled has increased in recent years, the Council and Board believed that the need for diligence is heightened with therapies approved via expedited pathways. The FDA was encouraged to utilize its existing authority to enforce penalties when these requirements are not met. Available penalties include modifying labeling information or withdrawing FDA approval. The Council and Board also encouraged public and private researchers to complete long-term evaluations of whether expedited pathways are achieving the desired effect of spurring innovation, decreasing costs and time associated with drug development, expanding patient access, and ensuring the safety and effectiveness of drug therapy.

In addition to the proposed policy, the Council identified several areas for ASHP action. The Society was encouraged to participate in advocacy activities related to proposed legislation that would create the LPAD pathway. Advocacy on this issue, which is being coordinated by the Infectious Diseases Society of America (IDSA) and The Pew Charitable Trusts, would be consistent with existing ASHP policy in this area (e.g., [ASHP endorsement](#) of IDSA’s *The 10 x 20 Initiative: Pursuing a Global Commitment to Developing Ten New Antibacterial Drugs by 2020* and the *Joint*

Statement on Antibiotic Resistance from 25 National Health Organizations and the Centers for Disease Control and Prevention). The Council also encouraged the *American Hospital Formulary System Drug Information (AHFS-DI)* to include information on a drug's approval pathway, when this information is available, and suggested that ASHP educate members about the benefits, limitations, and practice implications of the expedited pathways via live or web-based education or an *AJHP* article. Finally, it was recommended that the Council on Pharmacy Practice consider whether these expedited pathways necessitate revisions to ASHP practice standards related to formulary management. The Board agreed that ASHP should pursue these activities as appropriate.



C. FDA Oversight of Laboratory-Developed Tests

- 1 To advocate that the Food and Drug Administration be granted increased authority to
- 2 regulate laboratory-developed tests as medical devices, including tests used for
- 3 pharmacogenetic testing; further,

- 4 To support development of a risk-based framework for regulatory oversight of
- 5 laboratory-developed tests that promotes innovation while providing a mechanism to
- 6 ensure that test results are reliable, reproducible, and clinically relevant; further,

- 7 To encourage expanded availability of commercially marketed pharmacogenetic tests
- 8 that would be available for use by laboratory and health care professionals to guide
- 9 drug therapy.

Rationale

The use of *in vitro* pharmacogenetic tests has become increasingly common as efforts continue to achieve the promise of personalized medicine. However, the current system of regulatory oversight of these and other laboratory tests used to guide drug therapy is complex and inconsistent. Some laboratory tests (e.g., companion diagnostics devices) receive premarket review and approval by the Food and Drug Administration (FDA) when the test is either developed in tandem with drug development or following the drug's approval. Other tests, commonly called laboratory-developed tests (LDTs), are proprietary tests that are developed and validated for use at specific laboratory facilities. These tests do not undergo premarket review and approval by the FDA. LDTs currently fall under a mixed system of oversight by the FDA and Centers for Medicare & Medicaid Services (CMS), which regulates these tests based on facilities' compliance to the Clinical Laboratory Improvement Amendments (CLIA). CLIA compliance serves as the primary mechanism for oversight, as the FDA has traditionally practiced discretionary authority, meaning that only a few of the most complex tests are scrutinized by that agency. While an LDT is monitored for validity and reliability at the laboratory where it is conducted, results may not be reproducible if the test is conducted at a different laboratory site. This variability complicates the interpretation

and application of this information in patient care. Therefore, ASHP advocates for the FDA to have increased authority to regulate these LDTs as medical devices to ensure that results are reliable, reproducible, and clinically relevant to patient care.

Development of a risk-based framework represents the ideal model to provide sufficient oversight while creating conditions that support continued innovation in this field. Further, the development of nationally validated and marketed tests that are available for use by laboratory and health care professionals is desirable. ASHP believes that this scenario would provide the most assurance to pharmacists and other health care professionals that the results of these tests are reliable, reproducible, and clinically relevant to patient care.

Background

The Council considered current oversight of laboratory testing used to guide disease diagnosis and drug therapy as part of a broader discussion on the role of pharmacogenetic testing and pharmacogenomics in cancer treatment. Genetic testing now plays an important role in predicting patients' susceptibility to many diseases, including cancer. Pharmacogenetic testing is increasingly used to predict response to drug products, including projecting the effectiveness and toxicity of these therapies. Further, pharmacogenomics, which focuses on developing strategies to compensate for patients' genetic differences, plays a substantial role in drug development. There was support for these and other approaches intended to fulfill the promise of personalized medicine. However, the Council expressed significant concern about the reliability and clinical applicability of pharmacogenetic tests that fall within the category of LDTs. The Board shared this concern.

LDTs are used to conduct an array of health-related assessments, but the majority are designed to assess genetic information, including DNA, RNA, chromosomes, and proteins. The FDA has authority over genetic diagnostic tests that are commercially marketed under the Medical Devices Amendments Act of 1976, including those that are classified as companion diagnostic devices. However, there has been considerable debate as to whether this authority extends to LDTs. The FDA has stated that it has oversight of LDTs, but to date has demonstrated regulatory discretion by focusing only on those tests that it deems most complex. However, in recent years, FDA officials have expressed the need for more oversight in this area due to the increasing complexity and expanded use of LDTs, as well as higher risk associated with their use in medical decision-making. In addition, these tests are now frequently used to manage patients in health care settings that are well outside the geographic region of the laboratory in which they were developed. FDA officials have noted that there are currently "thousands of different LDTs" available.

Since 2010, the FDA has issued several statements indicating the Agency's intent to increase oversight of LDTs and noting that a risk-based framework is under development. The Council and Board supported the FDA's call for increased regulatory oversight in light of concerns as to whether the current oversight systems result in testing that is reliable, reproducible, and clinically relevant to patient care. Clinically significant variation in test results has been reported when the same sample is tested at different laboratories. The Council considered if this variability was similar to variances in reported results for other tests (e.g., INR), but noted that those variances are reported as a range that is useful to support clinical interpretation. Range information is absent with pharmacogenomic LDTs, and this leads to uncertainty when attempting to apply the results to patient care (e.g., determining susceptibility, adjusting doses). The Council

stated that this is especially problematic when using high-risk LDTs, such as those used to diagnose and treat cancer. The Board agreed.

Policy statements from the American Society for Clinical Pathology (ASCP) and College of American Pathologists (CAP) call for assurance that LDTs are of high quality, reliability, and safety to support clinical practice, but also stress the need for a regulatory framework that provides sufficient oversight without hindering innovation or preventing patient access. The Council and Board supported the concept of a risk-based oversight framework as outlined by FDA, ASCP, and CAP. ASCP and CAP have also identified a need for independent entities (e.g., accrediting bodies, international agencies) to provide a neutral source of oversight in addition to the oversight provided by FDA and CMS. The Council and Board did not offer a specific recommendation as to whether the proposed addition of independent third-party oversight was necessary.

Other stakeholders, including advisory committees established by the National Institutes of Health and the Department of Health and Human Services (DHHS), have called for additional oversight of these tests. The DHHS advisory committee stated that the “FDA should address all laboratory tests, regardless of how they are produced (i.e., as a commercial test kit or laboratory-developed test) in a manner that takes advantage of its current experience.” However, other stakeholders, including the American Clinical Laboratory Association, have opposed increased FDA oversight, citing a lack of jurisdiction given that these tests are not commercially distributed, concerns about increased burden on the laboratory industry, and the potential for decreased patient access to these tests.

While there is ongoing debate among external stakeholders about whether and how enhanced oversight should exist, the Council and Board were strongly supportive of the overall need for more oversight. There was also a desire to move toward an environment where more of these tests were commercially available for use in the laboratory setting when ordered by a health care professional. The Council and Board believed that standardization of these tests would support greater confidence in their use.

As part of the overall discussion of personalized medicine and cancer treatment, the Council noted that knowledge in this area has increased substantially since the human genome was fully sequenced in 2003. Information on disease state biomarkers, mutations, selective pressure, and drug resistance has become essential in guiding cancer treatment. While oncology has typically been viewed as the cutting edge of personalized medicine, cardiovascular disease and other conditions are expected to realize substantial gains in the near future. It was noted that while genetic testing may add upfront costs to disease management, these strategies can result in better patient outcomes and significant overall savings when the tests are used effectively. The Council believed that studies of conditions with specific genetic features will result in smaller patient populations in preclinical trials and unique challenges in interpreting and applying this information to patient care. The Board agreed with this assessment. Therefore, the importance of incorporating pharmacogenetic and pharmacogenomic information in drug information databases, including *AHFS DI* and information technology systems was noted. The Council and Board expressed continued support for existing ASHP policy 1104, [Pharmacogenomics](#), which describes the leadership role of pharmacists in this emerging area of practice.



D. Ensuring Effectiveness, Safety, and Access to Orphan Drug Products

- 1 To encourage continued research on and development of orphan drug products;
- 2 further,
- 3 To advocate for the use of innovative strategies and incentives to expand the breadth
- 4 of rare diseases addressed by this program; further,
- 5 To encourage postmarketing research to support the safe and effective use of these
- 6 drug products for approved and off-label indications; further,
- 7 To advocate that the Food and Drug Administration maintain a publicly available and
- 8 comprehensive list of orphan drug products and their approved indications; further,
- 9 To urge health policymakers, payers, and pharmaceutical manufacturers to develop
- 10 innovative ways to ensure patient access to orphan drug products.

(Note: This policy would supersede ASHP policy 0715.)

Rationale

The U.S. Orphan Drug Act of 1983 and similar programs in other countries have greatly expanded the number of therapies available to treat rare diseases through the use of financial and other incentives that encourage drug manufacturers to develop medications for limited patient populations. Despite the overall success of orphan drug programs, concerns have been raised about the breadth of drugs approved through these mechanisms. Although there are more than 7000 designated orphan diseases in the United States, oncology drugs represent approximately 33 percent of all orphan drug approvals. ASHP believes that there is a significant need to develop a more comprehensive approach to orphan drug development in order to encourage drug manufacturers to expand the breadth of rare conditions treated by these therapies.

Once an orphan drug is approved, it may be used without restrictions, and these therapies are frequently used to treat patients and conditions that were not assessed during pre-approval clinical studies. While this use can spur innovation and lead to advances in the treatment of common diseases, ASHP believes that this use is also associated with the potential for increased patient harm given the small patient populations and other characteristics common to studies used to support orphan drug approval. Research is necessary to evaluate the safety and effectiveness of these therapies under real-use conditions. In addition to manufacturer-conducted research, ASHP encourages private and public sector research in order to provide sufficient evidence to support off-label use.

Currently, there is no publicly accessible mechanism to readily identify orphan drug products and their associated approved indications. This lack of information often leads to

confusion as to whether an orphan drug is being used for a labeled indication or other condition. ASHP advocates that the FDA should develop and maintain this information in a database or other format that is readily accessible to the public. Availability of this information would facilitate risk-versus-benefit assessments by clinicians and patients and provide information necessary to determine if a specific drug and indication will be covered by payers.

ASHP is concerned about the high cost of these therapies, which contributes to increased health care costs and potentially decreases patient access, especially among those who are under- or uninsured. Further, some orphan drugs have later been discontinued by the drug manufacturer—an occurrence that often leaves patients with rare conditions without a treatment alternative. It is essential that stakeholders (e.g., health policymakers, payers, and pharmaceutical manufacturers) continue efforts to provide patient access to these therapies, including developing strategies to ensure that the cost of these therapies does not create an unreasonable barrier to patient access.

Background

The Council voted and the Board agreed to recommend amending policy 0715 as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To encourage continued research, on and development, ~~and marketing~~ of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of these drug products for approved and off-label indications; further,

To advocate that the Food and Drug Administration maintain a publicly available and comprehensive list of orphan drug products and their approved indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products; ~~further,~~

~~To support public policies that ensure that the cost of orphan drug products does not preclude reasonable patient access to these agents.~~

The Council considered what was described as the overwhelming success of the U.S. Orphan Drug Act of 1983. In the years that followed enactment, other regions, including Japan and Europe, launched similar programs. The Council and Board found that orphan drug programs have provided clinical benefit to patients, as well as significant financial value to the pharmaceutical industry. Analyses provided in a [2013 report from EvaluatePharma](#), a global research firm that evaluates the pharmaceutical industry from the perspective of financial markets, projected that orphan drug products will account for approximately 16 percent of all branded prescription sales in 2018. The report also found that Phase III drug development costs are substantially lower for these products than for non-orphan drugs, and that the return on investment for orphan drug

products is 1.7 times greater than the return on investment for non-orphan drugs. In the United States, this favorable return on investment is due, in part, to a 50 percent tax credit that drug manufacturers receive on research and development costs, as well as the availability of research grants from government entities, including the National Cancer Institute, to complete Phase I, II, and III studies. User fee applications are also waived. In addition, costs associated with clinical trials may be reduced due to the decreased size of study groups drawn from the smaller overall patient population affected by the disease or condition. These and other factors have incentivized development of orphan drug products. Overall, the Council and Board supported the U.S. Orphan Drug Act. However, there is a need to develop new strategies, which might include financial incentives, to broaden the extent of rare diseases treated by these therapies. The Council came to the conclusion that there is an over-emphasis on some diseases based on the fact that drugs used to treat cancer represent approximately 33 percent of all approved orphan drugs. The Board agreed with this assessment.

The Council discussed at length the patient care ramifications of the more narrowly designed clinical trials that support FDA approval of orphan drug products. Given these small study populations, the full side effect profile of these drugs is not obtained through pre-approval studies. In addition, the Council noted that it is often difficult to distinguish side effects of the drug from events related to the disease itself. These evidence limitations present a challenge in determining appropriate use of these therapies, especially as use expands beyond labeled indications. For example, data from broader use of rituximab demonstrated an increased incidence of hepatitis B recurrence and the product labeling now includes information about this risk. (Of note, EvaluatePharma projects that worldwide sales of rituximab will make it the number one orphan drug in 2018.) Based on these challenges, the Council and Board strongly encouraged postmarketing studies to ensure that there is adequate evidence to guide use of these drugs for labeled and unlabeled indications. Given the expanded use of some orphan drugs, private and public sector research will be needed to supplement postmarketing research conducted by drug manufacturers, which is generally more heavily focused on labeled indications or conditions for which a new indication is being sought.

To support this work and improve the availability of information to guide patient care, the Council and Board recommended that the FDA be required to develop and maintain a publicly available list of orphan drugs and their approved indications. In addition, *AHFS DI* was encouraged to include this information within drug monographs. The Council also briefly discussed the recent Department of Health and Human Services' Office of Pharmacy Affairs [final rule](#) that allows facilities that are eligible for 340B pricing to purchase orphan drugs at discounted prices. However, this was described as difficult, if not impossible, to implement given the absence of a list to determine a drug's orphan status and approved indications.

The Council compared characteristics of the U.S. Orphan Drug Act to similar programs in other countries. The population criteria used to determine a rare disease varies slightly between countries, with the United States permitting a slighter higher ratio of affected patients to general population than other countries. To be granted orphan drug status in the United States, a drug must be intended to treat a condition that occurs in fewer than 200,000 patients, which translates to slightly more than 6 in every 10,000 individuals. In Japan and Europe, these ratios are roughly 4 and 5 for every 10,000 individuals, respectively. There are more than 7000 conditions designated as rare diseases in the United States. According to an [analysis](#) authored by Wellman-Labadie and

Zhou and published in *Health Policy* in 2010, just over 2000 drugs in the United States have been granted orphan drug status, with only 352 of these drugs having ultimately received FDA approval.

In terms of financial incentives, the market exclusivity period is extended to 10 years in other countries, as compared to seven years in the United States. A primary criticism of orphan drug programs, regardless of country, is the fact that some orphan drugs have become “blockbuster drugs.” Examples of blockbuster orphan drugs, which are defined as those that exceed global sales of \$100 million in U.S. dollars, include epoetin alpha, interferon beta, and imatinib. In the United States, drug manufacturers retain the full financial benefits defined under the Orphan Drug Act, even if the orphan drug experiences expanded or off-label use following the initial drug approval. However, this is not the case in other countries. For example, in Japan, drug manufacturers pay a 1 percent tax on revenues from orphan drugs that have sales in excess of 100 million yen per year until the amount paid reaches the amount the company received in government subsidies. The Council and Board noted these geographic inconsistencies and expressed interest in unifying orphan drug definitions and requirements across countries given the global nature of drug development. However, it was noted that this is unlikely to occur in the absence of a substantial and coordinated international effort. Further, there was concern about altering the current U.S. standards, noting that the *Health Policy* analysis found a significant decrease in the submission of U.S. orphan drug applications in the years following previous Congressional proposals to alter financial incentives. In addition, while blockbuster orphan drugs are the subject of significant controversy, only 9 percent of orphan drugs, or 43 products, have achieved this status, and only 11 of those products received blockbuster status prior to the conclusion of the seven-year market exclusivity period. In addition, many of these products hold two or more orphan drug indications, which expand the potential market. These facts indicate that blockbuster status may be the exception, not the rule. Therefore, in order to preserve innovation, the Council and Board did not recommend any changes to financial incentives at this time.

The Council and Board supported existing language in policy 0715 that calls for policies and strategies that ensure patient access to therapies by supporting reasonable costs for orphan drugs. The high cost of these therapies remains a significant issue. In addition, manufacturers have discontinued drug products for reasons that may include profit consideration. These decisions often leave patients with no viable alternative to treat a rare condition. The final clause in the existing policy was deleted due to duplication of concepts in the previous clause.

Finally, the Council stated that there is a need for clinician education to ensure appropriate use of these therapies given the complexity of orphan drug approval and use. ASHP was encouraged to address information needs related to effectiveness, safety, and reimbursement issues via the Society’s available mechanisms for providing information and education to members. The Board agreed with these recommendations.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing ASHP policies, 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.)

- [Safe and Effective Use of Heparin in Neonates](#) (0912)

Endorsement of Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines for Thiopurine Methyltransferase Genotype and Thiopurine Dosing

The Council recommended and the Board voted to endorse the CPIC [Guidelines for Thiopurine Methyltransferase Genotype and Thiopurine Dosing](#).

The Council reviewed this guideline, which provides information on using thiopurine methyltransferase (TPMT) genotyping tests to evaluate for variations in metabolism of thiopurines— azathioprine, mercaptopurine, and thioguanine. The Council recommended endorsement of the guidelines because they provide practical information about managing these drug therapies. Deficiencies of TPMT result in heightened potential for serious adverse drug events, even when short courses of the therapy are provided. For this reason, the Council and Board supported recommendations in the guidance that could prevent potentially devastating side effects, such as myelosuppression. The test, which identifies the risk of severe myelosuppression in homozygous patients (i.e., those with two nonfunctional TPMT alleles), is considered highly predictive. The guidance also provides weight-based dosage adjustments, which is beneficial given that mercaptopurine is more commonly used in pediatric patients. While the test contributes to upfront cost, its use can reduce overall costs through avoidance of patient morbidity and costs associated with treatment for myelosuppression. The Council and Board appreciated that the guidelines, which were first published in 2011, were updated in 2013 to include information on new supportive studies in the supplemental materials, even though the recommendations themselves were not altered by this new evidence.

This is the third Clinical Pharmacogenetics Implementation Consortium (CPIC) guidance that ASHP has endorsed. CPIC was formed by the National Institutes of Health's Pharmacogenomics Research Network and the Pharmacogenomics Knowledge Base in 2009. One goal of CPIC is to provide peer-reviewed, evidence-based, and freely accessible guidelines for drug–gene pairs to support the translation of pharmacogenomic information from research to clinical practice. Previous Council recommendations in 2012 and 2011 subsequently led to Board approval and [ASHP endorsement of guidelines](#) on using cytochrome P450 2D6 genotyping to manage codeine therapy and clopidogrel and other antiplatelet therapies, respectively. As noted with previous endorsement recommendations, the Council appreciated that the guidance did not take a stance on whether the test should or shouldn't be used, but rather focused on how to interpret the test if it is done. This approach is preferred given ongoing barriers to the use of pharmacogenomic tests (e.g., potential delays in access to results, limited access in small and rural health care settings).

ASHP Therapeutic Position Statement on Prevention and Treatment of Osteoporosis in Adults

The Council recommended and the Board agreed to discontinue the *ASHP Therapeutic Position Statement on Prevention and Treatment of Osteoporosis in Adults*. The Council reviewed the therapeutic position statement (TPS), which was approved by the Board of Directors in 2007, as part of sunset review, noting it was intended to address an identified gap between evidence on the prevention and treatment of osteoporosis and the implementation of these strategies in clinical practice. Specific goals of the TPS were to assist pharmacists in the (1) identification of at-risk individuals, (2) selection of therapies to prevent or minimize morbidity and mortality associated with osteoporosis, and (3) provision of patient education. The Council noted several topic areas in which the current TPS is outdated, including the absence of more recent information on drug side effects (e.g., hypocalcemia associated with denosumab use). The Council also reviewed osteoporosis guidelines available from other organizations, including the National Osteoporosis Foundation, the American Association of Clinical Endocrinologists, and the American College of Obstetricians and Gynecologists. Given the quality of these guidelines, the Council questioned whether ASHP members would be likely to consult the ASHP TPS as a primary resource. The more expansive information on diagnostic testing provided in the competing documents was also viewed favorably. In light of these considerations, the Council believed that ASHP resources would be better used to develop guidance in other clinical areas where a greater member need is identified, rather than using limited resources to revise the existing guidance. Therefore, the Council recommended that the current TPS be discontinued, and the Board agreed.

Practice-Based Strategies to Prevent Abuse of Controlled Substances

The Council recommended and the Board voted to collaborate with interdisciplinary stakeholders to develop, disseminate, and encourage adoption of practice-based strategies that address the public health epidemic of prescription drug abuse.

The Council discussed ongoing concerns about prescription drug abuse in the United States in the context of ASHP's existing policy in this area. There was support for ASHP policy 1106, [Pain Management](#), which describes the importance of pain management as an integral part of patient care. In addition to supporting patient access to pain therapies, this policy advocates that pharmacists play a leadership role in "efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse." The Council strongly encouraged ASHP to increase the Society's activities aimed at addressing this public health issue, with a focus on team-based interventions that balance the need for abuse deterrents with the need to ensure patient access to treatment. The Board supported this recommendation.

In developing this recommendation, the Council reviewed data from the Centers for Disease Control and Prevention that indicate that more deaths now occur from overdoses of opioid pain relievers than from overdoses of cocaine and heroin combined. Abuse of these therapies remains a public health issue despite implementation of various strategies to address the problem. The majority of these interventions provide regulatory changes at the state or national level (e.g., prescription drug monitoring programs [PDMPs], rescheduling of drugs associated with extensive abuse, and REMS). While these interventions have resulted in some

improvement, prescription drug abuse continues to be associated with significant morbidity and mortality.

The Council considered the role of clinical interventions in addressing prescription drug abuse and noted parallels between these efforts and antibiotic stewardship principles. The Council reviewed evidence evaluating the effectiveness of clinical tools (e.g., screening tools, urine drug testing, and patient-provider contracts), as well as corporate screening programs that have been launched in the outpatient setting with the intent of curbing abuse. The Council found that the available clinical tools are effective to varying degrees, and the Board agreed. For example, urine drug testing can identify dose escalations initiated by the patient rather than the clinician and the potential for drug diversion when drug metabolites are absent. However, these tests can be manipulated by patients and adherence is low. Further, testing results are not always available to pharmacists who practice in the outpatient setting. Screening tools that assess patients for actual or potential aberrant drug-related behaviors have also demonstrated effectiveness in published studies. Screening tools that determine a risk level or category may be the most useful clinical tool; however, it was noted that these interventions are time- and labor-intensive. The Council also considered whether dosing limitations are an effective strategy to curb abuse. While a recommendation on dosing limits was not provided, the Council stated that there is evidence that patients being treated for non-cancer pain who do not respond to adequate treatment trials are unlikely to achieve pain relief with dose escalations. Finally, the Council cautioned against actions that were described as knee-jerk responses that force clinicians into a policing role or pit the efforts of one clinician against another. The Board agreed with the Council's assessments.

Overall, the Council and Board found that clinical interventions, especially those that provide interprofessional collaboration, remain underutilized. Therefore, it was recommended that ASHP collaborate with other interested stakeholders, including the American Medical Association, to improve the use of controlled substances to treat non-cancer pain while addressing the public health epidemic of prescription drug abuse. Proposed elements of this initiative would include initial work to identify areas to target for intervention based on prescribing trends and other factors, followed by the development and dissemination of standards or tools to support collaborative care. Education was also recommended as a key component of the collaborative effort. The recommended strategies should address the continuum of care, noting that prescription drug abuse can follow initiation of pain therapies in the inpatient setting that are not effectively managed following the transition of care.

Finally, the Council recommended use of other strategies to address prescription drug abuse, including encouraging the preferential use of tamper- and abuse-resistant drug products as more of these products become available. Standardization of PDMPs was also encouraged, including consideration of mechanisms that would integrate data from government programs (e.g., Veterans Administration, Indian Health Services). The Board supported these recommendations.

Appropriate Use of Acetaminophen Therapies

The Council recommended and the Board voted to develop guidance and other resources that address the appropriate use of acetaminophen therapy for patients treated in the inpatient setting.

The Council and Board recommended that ASHP survey members regarding current practices for use of oral and intravenous acetaminophen in the inpatient setting and use this information to inform development of guidelines that summarize available evidence on the safety and effectiveness of these therapies and describe strategies for ensuring appropriate use. The Council identified a need for this guidance after reviewing evidence, including a [study by Zhou et al.](#) published in the December 2012 issue of *Archives of Internal Medicine*, demonstrating that supratherapeutic dosing of acetaminophen occurs in the inpatient setting. Prior to these studies, the occurrence of acetaminophen toxicity has most commonly been associated with outpatient use, where consumers may exceed the maximum daily dose due to dosing errors or failure to recognize the presence of acetaminophen in nonprescription products. This new evidence demonstrates that doses exceeding the maximum daily dose occur in the inpatient setting, despite the use of CPOE and other technologies intended to prevent such events. The Council agreed that higher-than-recommended doses do occur and noted that their incidence may be increasing due to the use of intravenous acetaminophen in surgical and perioperative settings, where gaps in information technology can limit provision of timely and accurate dosing information to other health care providers. Although the guidelines would focus on inpatient use, they should also address use of these therapies across the continuum of care as the patient is admitted and discharged from the inpatient setting.

A significant portion of the Council discussion focused on use of intravenous acetaminophen. There was concern about prescriber perceptions of improved effectiveness and safety with the intravenous formulation as compared to oral acetaminophen and other treatment options. The Council strongly believed that this perception results from misinterpretation of data provided in marketing materials. A 2012 [article by Yeh and Reddy](#) published in *Pharmacotherapy* provides a more comprehensive review of evidence. The Council found that many of the available studies are of poor quality because they involve small patient populations or use placebos or drugs that would not be considered standard of care as the comparator therapy. The Board agreed with this assessment. In addition, the Institute for Safe Medication Practices has documented harm when pediatric patients have received an overdose of this product, which is only available in a high-concentration formulation. In light of these concerns, the Council recommended that facilities develop protocols through their pharmacy and therapeutics committees to ensure appropriate use, and the Board concurred. The high cost of these therapies is another factor supporting the need to ensure appropriate use. Despite these concerns, it was noted that intravenous acetaminophen has an appropriate place in therapy (e.g., for immediate post-operative use, for patients who are NPO or opioid allergic or intolerant, and in the treatment of fever of unknown origin). Rectal administration may also be appropriate in many of these situations and this route of administration is likely to offer a more cost-effective alternative.

In addition to addressing practice challenges identified by the member survey, the guidelines should address the following topics: pharmacokinetic parameters and evidence evaluating their clinical relevance, the role of acetaminophen in multimodal pain management, effect on narcotic intake and occurrence of side effects, available evidence regarding length of stay and other patient outcomes, evidence of cost effectiveness, and preparation and administration practices to ensure safe use of the intravenous formulation. Recommended areas to assess in the survey include usage trends for the oral and intravenous formulations and use of information technology and other strategies to prevent supratherapeutic dosing. Specific to the intravenous

formulation, survey questions should assess formulary status, restrictions, and criteria for use, as well as oversight of the product's use in outpatient clinics.

Clinical Management of Drug Products Associated with QT Interval Prolongation

The Council recommended and the Board voted to develop guidance and other resources to assist pharmacists in the risk assessment and clinical management of drug products associated with QT interval prolongation.

The Council considered challenges in the risk assessment and clinical management of drugs associated with QT interval prolongation as part of a broader discussion of the FDA approval and subsequent use of these therapies in clinical practice. QT interval prolongation can result in drug-induced torsades de pointes (TDP). TDP is a rare, but significant arrhythmia that can result in sudden cardiac death. There are several criteria to identify patients at higher risk of developing TDP, including hypokalemia, hypomagnesemia, concomitant use of other medications that prolong the QT interval or inhibit metabolism of the initial therapy, and female sex. These factors are useful for determining whether a medication should be used and, if so, the extent to which EKG and other monitoring is required. However, the Council noted that this process remains an inexact science that is further complicated by unique clinical circumstances. The Board agreed with the assessment. For example, two medications known to prolong the QT interval may not result in the anticipated synergistic effect on the QT interval when used concomitantly. In other instances, the FDA and drug manufacturer may issue new product labeling for a drug that an individual patient has been taking for an extended duration of time without any occurrence of an arrhythmia or other adverse drug event. Recent decreases in the dosing limits for citalopram illustrate this dilemma. There are also rare occurrences when a drug associated with QT interval prolongation in preclinical trials is the only viable treatment for a patient with coexisting risk factors for TDP. In these scenarios, the appropriate course of action is based on an assessment of risk versus benefit for the individual patient. While no absolute guidance can be provided in these scenarios, guiding principles can be applied. Therefore, it was recommended that ASHP develop guidance that offers a process-oriented perspective on managing these patients, including strategies for patient screening and assessment and documentation in the patient medical record. In addition to describing this process, the guidance should describe the FDA's current preclinical model for assessing the potential for TDP, including its limitations.

Related to those limitations, the Council considered ongoing collaboration between the FDA and a research consortium that is developing a new paradigm for preclinical testing of drugs in development to assess the potential to cause TDP. Current testing models focus on the potential for QT interval prolongation. However, this measure is only a surrogate marker, and the exact nature of the relationship between QT interval prolongation and the risk of TDP has not been well defined. Many drugs that demonstrated QT prolongation in preclinical trials have not demonstrated proarrhythmic potential in the postmarketing clinical environment. However, the Council noted that, based on this uncertainty, drug manufacturers may abandon development of drugs that exhibit QT interval prolongation, potentially resulting in the loss of drug products with clinical benefit. The Council and Board viewed favorably the work of this collaborative that could increase the reliability of preclinical testing and result in more consistent product labeling that provides clinicians with greater insight on patient-care implications. However, it was noted that additional research and thorough validation of the proposed model will be necessary prior to

implementation. ASHP was encouraged to monitor for ongoing activities in this initiative, including opportunities for the Council to contribute to the Society's official comments when the model is available for public comment. In the interim, the recommended guidance will address a knowledge gap in the clinical management of patients receiving these drug products.

Other Council Activity

ASHP Therapeutic Position Statement on Cessation of Tobacco Use

The Council reviewed the [ASHP Therapeutic Position Statement on Cessation of Tobacco Use](#) as part of sunset review. This TPS, which was approved by the Board of Directors in 2008, was intended to encourage pharmacists to take an active role in tobacco cessation efforts through work to identify tobacco users and provide evidence-based therapy, including pharmacotherapy and behavioral interventions. The Council stated that the guidance requires general updates to reflect current evidence. The Council recommended devoting ASHP resources to the proposed revision, noting that there is still a significant leadership role for pharmacists in this area in light of The Joint Commission's new [Tobacco Cessation Performance Measure Set](#) that took effect in January 2012. While those measures are voluntary, the Council believed that these standards illustrate the importance of tobacco cessation efforts. In addition, a tobacco-use screening and cessation intervention measure is recommended for adult care as part of CMS's 2014 core measures. Based on this information, the Council recommended that the document be revised to reflect current evidence. In addition, the controversy regarding the marketing and use of electronic cigarettes should be addressed.

Recommendations for ASHP Guidelines Development

In June 2013, the National Heart, Lung, and Blood Institute (NHLBI) announced that it would discontinue development of clinical guidelines, an activity that the institute (which is housed in the National Institutes of Health) had engaged in since 1977. Clinicians have come to rely on NHLBI guidelines that address diseases that have a high prevalence and patient impact (e.g., hypertension, high cholesterol). ASHP and other guidelines developers have also used NHLBI guidances as a basis for the focused clinical guidelines that they develop. In the same announcement, NHLBI described a new focus on preparing systematic reviews that will be made available to other stakeholders to develop independent guidelines. The Council advised ASHP regarding the practice impact of NHLBI's new approach and recommended strategies for ASHP's ongoing work in guidelines development.

While the discontinuation of NHLBI guidelines represents a significant resource gap, it also provides an opportunity for ASHP to continue efforts to expand the Society's work in collaborative guidelines development. This approach was recommended in the 2010 Institute of Medicine report, [Knowing What Works in Health Care: A Roadmap for the Nation](#). It is also consistent with ASHP's recent work to develop multi-stakeholder guidelines on surgical antimicrobial prophylaxis, therapeutic monitoring of vancomycin, and treatment of pain, agitation, and delirium. In addition, the American College of Cardiology (ACC) and the American Heart Association (AHA)—the organizations that have agreed to lead development of several previous NHLBI guidelines related to cardiovascular health—use a widely accepted standard for grading guidelines

recommendations. Processes established by these organizations to ensure transparency and manage conflicts of interest were also considered best practices. For these reasons, ASHP was encouraged to pursue opportunities to collaborate with ACC and AHA in the development of those guidelines. The Council also suggested that ASHP continue to endorse guidelines authored by other organizations when these guidelines address the needs of ASHP members and meet established quality standards. Ongoing development of therapeutic position statements to address practice gaps in drug use and others topics specific to pharmacy practice was also encouraged. Finally, it was recommended that ASHP consider dissemination and educational activities an essential and necessary component of the Society's guideline development activities.



The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

Board of Directors Report on the Council on Education and Workforce Development

The Council on Education and Workforce Development is concerned with ASHP professional policies related to the quality and quantity of pharmacy practitioners in hospitals and health systems. 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 W. Bush, *Board Liaison*

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Policy Recommendations



A. Cultural Competency and Cultural Diversity

- 1 To promote the development of cultural competency of educators, practitioners, residents, students, and technicians; further,
- 3 To foster awareness of the impact that an ethnically and culturally diverse workforce
- 4 has on improving health care quality.

(Note: This policy would supersede ASHP policies 0314 and 0409.)

Rationale

The United States is rapidly becoming a more diverse nation. Culture influences a patient's belief and behavior toward health and illness. The representation of many of these diverse groups within the health professions is far below their representation in the general population. According to the Institute of Medicine, increasing racial and ethnic diversity among health care providers is associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better educational experiences for health professions students.¹

Cultural competence can significantly affect clinical outcomes. Research has shown that the overlooking of cultural beliefs may lead to negative health consequences². According to the National Center for Cultural Competency there are numerous examples of benefits derived from the impact of cultural competence on quality and effectiveness of care in relation to health outcomes and well-being.³

The underrepresentation of minorities among health care providers is often considered to be one of the contributing factors to health disparities in these populations.⁴ The Report of the ASHP Ad Hoc Committee on Ethnic Diversity and Cultural Competence supports ways to

¹ Smedley BD, Butler AS, Bristow LR, eds. In the nation's compelling interest: ensuring diversity in the health-care workforce. Washington, DC: National Academies Press; 2004.

² Administration on Aging. Achieving cultural competence. A guidebook for providers of services to older Americans and their families. Available <http://archive.org/details/achievingcultura00admi> (accessed October 17, 2013)

³ Goode TD, Dunne MC, Bronheim SM. The evidence base for cultural and linguistic competency in health care. The Commonwealth Fund; 2006. Available http://www.commonwealthfund.org/usr_doc/Goode_evidencebasecultlinguisticcomp_962.pdf (accessed October 17, 2013)

⁴ Smedley BD, Butler AS, Bristow LR, eds. In the nation's compelling interest: ensuring diversity in the health-care workforce. Washington, DC: National Academies Press; 2004.

raise awareness of the importance of cultural competence in the provision of patient care so that optimal therapeutic outcomes are achieved in diverse populations.⁵

Background

The Council voted and the Board agreed to recommend amending ASHP policy 0314, Cultural Competence, and policy 0409, Cultural Diversity Among Health Care Providers. Policy 0314 reads as follows:

To foster cultural competence among pharmacy students, residents, and practitioners and within health systems for the purposes of achieving optimal therapeutic outcomes in diverse patient populations.

Policy 0409 reads as follows:

To foster awareness of the cultural diversity of health care providers; further,

To foster recognition of the impact that cultural diversity of health care providers may have on the medication-use process; further,

To develop the cultural competence of pharmacy practitioners, technicians, students, and educators.

In 2012, the Council voted to recommend combining these concepts into a single policy. After considerable discussion, the 2013 House of Delegates concluded that the proposed policy wording was not clear and voted to refer the proposed policy back to the Council for additional review and clarification. The 2013 Council members generally felt that policy 0314 is a good policy, but it does not specify pharmacy technicians; and that policy 0409 does include technicians, but has some duplicative wording with policy 0314. The Council crafted a new single policy intended to supersede policies 0314 and 0409, and the Board concurred.

⁵ Report of the ASHP Ad hoc committee on ethnic diversity and cultural competence. *Am J Health-Syst Pharm.* 2005; 1924-30.



B. Credentialing, Privileging, and Competency Assessment

- 1 To support the use of post-licensure credentialing, privileging, and competency
- 2 assessment to practice pharmacy as a direct patient-care practitioner; further,
- 3 To advocate that all post-licensure pharmacy credentialing programs meet the guiding
- 4 principles established by the Council on Credentialing in Pharmacy; further,
- 5 To recognize that pharmacists are independently responsible for maintaining
- 6 competency to practice in direct patient care.

(Note: This policy would supersede ASHP policy 0006.)

Rationale

Pharmacists engaged in direct patient care should possess the education, training, and experience necessary to function effectively, efficiently, and responsibly in that role. As their role in direct patient care has increased, pharmacists have recognized that they are independently responsible for maintaining their credentials and competencies. Currently, no specific objective measures are available for determining competence to provide direct patient care, however. Until such measures are available, pharmacists can establish their competence through post-licensure education, training, and certification, and health care organizations can ensure that practitioners with the right skills are matched to the scope of practice expected through competency assessment and their credentialing and privileging processes.

Although many avenues of credentialing and competency assessment currently exist, hospital and health-system credentialing and privileging of pharmacists is a relatively recent phenomenon. ASHP and the Council on Credentialing in Pharmacy (CCP) are in agreement that pharmacists should be expected to participate in credentialing and privileging processes to ensure they have attained and maintain competency to provide the scope of services and quality of care that are required in their practices (Council on Credentialing in Pharmacy [Guiding Principles for Post-Licensure Credentialing of Pharmacists](#), February 2011.) To ensure the quality of post-licensure credentialing programs, they should be required to adhere to the guiding principles developed by CCP.

Note that several definitions are integral to proper understanding of this policy (definitions taken from the Council on Credentialing in Pharmacy, [Credentialing in Pharmacy: A Resource Paper](#), except as noted):

Credential: documented evidence of professional qualifications.

Credentialing: (1) the process of granting a credential, and (2) the process by which an organization obtains, verifies, and accesses an individual's qualifications to provide patient care services.

Privileging: the process by which an oversight body of a health care organization or other appropriate provider body, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that setting.

Competence: The ability of the individual to perform his/her duties accurately, make correct judgments, and interact appropriately with patients and colleagues.

Competency: A distinct knowledge, skill, attitude, or value that is essential to the practice of a profession.

Direct patient care: involves the pharmacist's direct observation of the patient and his or her (i.e., the pharmacist's) contributions to the selection, modification, and monitoring of patient-specific drug therapy. This is often accomplished within an interprofessional team or through collaborative practice with another health care provider. (American College of Clinical Pharmacy definition, as endorsed in: Council on Credentialing in Pharmacy. [Scope of contemporary pharmacy practice: roles, responsibilities, and functions of pharmacists and pharmacy technicians.](#))

Background

The Council voted and the Board agreed to recommend amending ASHP policy 0006, Pharmacist Credentialing, as follows (underscore indicates new text; ~~strike through~~ indicates deletions):

~~To support the position that credentialing is a voluntary professional activity distinct and separate from the licensing process; further,~~

~~To endorse the goals and standards based approach to credentialing being pursued by the Council on Credentialing in Pharmacy (CCP); further,~~

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

~~To support the position~~ advocate that all ~~widely accepted~~ post-licensure pharmacy credentialing programs must meet quality standards that are being the guiding principles established by CCP the Council on Credentialing in Pharmacy; further,

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

Post-licensure education, training, and certification are ways that pharmacists establish their competence to provide patient care services within a defined scope. The Council and Board agreed that the word "voluntary" dated ASHP policy 0006 and considered that an important reason to revise the policy. Council members also felt the wording in policy 0006 related to

“quality standards” to be important. The Council and Board agreed to reference “the guiding principles established by the Council on Credentialing in Pharmacy” to advocate for a high level of program quality. The Council and Board also felt it is important to specify that pharmacists are independently responsible for maintaining their credentials and competencies to practice in direct patient care roles.

There was discussion regarding how likely it is that privileging and credentialing will take place in the next two years. Council members agreed that credentialing and competency is currently widespread, but privileging is not as common in many settings. The Council and Board support privileging and felt that this is a direction pharmacy is going, even if there is no definite timeline. The Council understood that the policy is visionary but agreed it is the right thing to do, and the Board concurred.

It was also noted that this policy will be helpful in efforts to change the pharmacy practice model. The Council believed that the policy could be used within health systems to encourage medical staff privileging committees to adopt privileging of pharmacists. Since many practice settings have not moved to a pharmacist privileging model, this policy will help support adoption. The Council also noted that this policy will not hinder states with collaborative practice acts and could be a foundation for beginning to develop objective methods for measuring competency for direct patient care.



C. Education About Patient Safety in the Medication-Use Process

To discontinue ASHP policy 0914, which reads:

- 1 To encourage colleges of pharmacy to include instruction on patient safety throughout
- 2 the medication-use process in the didactic curriculum and during experiential
- 3 education.

Background

As part of sunset review, the Council discussed policy 0914. The Council and Board agreed that because patient safety is clearly a focus of pharmacy education and is included in Accreditation Council for Pharmacy Education (ACPE) accreditation standards, this policy is no longer needed and recommended discontinuation.



D. ASHP Statement on Continuing Education

To discontinue the *ASHP Statement on Continuing Education* ([Appendix](#)).

Background

The statement was last reviewed in 2003 but was written in the 1980s. The language in the statement is outdated, and the Council and Board concluded there was no longer a need for the statement.

The Council discussed the history of the statement and noted that it focuses on ASHP's role as a continuing education (CE) provider. The Council questioned whether the statement helps the membership in a meaningful way, given that ASHP has a [policy on continuing professional development](#) (CPD) and is an ACPE-accredited provider of CE, meaning that ASHP must meet ACPE standards to continue to be accredited.

The Council asked if ASHP Department of Educational Services has a mission statement. The ASHP Mission Statement and Goal on Continuing Pharmacy Education (CPE) were read to the group as follows:

Mission: *To provide education for pharmacists, pharmacy technicians, and related healthcare professionals that is contemporary and based on the best available evidence and reflects best practices.*

Goal: *The goal of ASHP's CPE program is to provide exemplary continuing education activities that meet the professional development needs of pharmacists, pharmacy technicians, and related healthcare professionals. ASHP's educational program improves the knowledge and skills of the target audiences to enable them to improve patient care; with special focus on optimizing the safety, effectiveness, and leadership of medication use.*

The Council acknowledged that the mission and goals addressed the substance of the statement. The Council and Board therefore concluded that the statement is no longer needed and should be discontinued.

The Council also discussed and the Board agreed that there would be value in a statement that describes how an ASHP member might use a repository to look for all of their professional development and an easier portal of entry to do their own CPD. The Council and the Board agreed that the Council should investigate development of an ASHP statement on continuing professional development, and if feasible, to present a draft statement to a future Council meeting.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing ASHP policies, 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.)

- [Pharmacy Student Experiences in Medically Underserved Areas](#) (0913)
- [Pharmacy Expertise in the Preparation and Handling of Injectable Medications](#) (0915)
- [Continuing Professional Development](#) (0916)
- [Pharmacy Residency Training](#) (0917)

Other Council Activity

ASHP Statement on the Role of Pharmacy Technicians in Health-System Pharmacy

The Council members reviewed the draft *ASHP Statement on the Role of Pharmacy Technicians in Health-System Pharmacy* prepared by the Section of Inpatient Care Practitioners and suggested ways the document could be strengthened.

Standardization of Criminal Background Checks for Students and Pharmacy Technician Students

The Council agreed that more standardization of criminal background checks would be ideal, but that different employers had different requirements about what is included in a check and how frequent those checks should be. The Council concluded that one universally accepted national background check is not feasible and therefore felt ASHP policy on the topic is not needed, noting that background checks are being completed, albeit with great variability.

Education and Training in Pharmacogenomics and Pharmacogenetics for Pharmacists and Student Pharmacists

The Council discussed how these topics are incorporated throughout the pharmacy curriculum, noting that it would be interesting to know how different colleges of pharmacy handled the topics for comparison and evaluation. Council members suggested that practicing pharmacists may not feel comfortable discussing genetic testing with patients. It was noted that many continuing education resources exist for those interested in learning more about the topic. As genetic testing kits increasingly become available over the counter, ambulatory pharmacists will need to be prepared to discuss results with patients. The Council reviewed ASHP policy 1104, [Pharmacogenomics](#), and encouraged the Council on Therapeutics to consider adding an ethics component to the policy.

Transitions of Care Training for Student Pharmacists and Residents

In The Joint Commission (TJC) standard on transitions of care, physicians and nurses are specifically mentioned, but pharmacists are not. The 2011 version of the ACPE standards for pharmacy school accreditation do not specifically address transitions of care. In the new Center for the Advancement of Pharmaceutical Education (CAPE) outcomes, however, this topic will be addressed in medication-use management. Currently, two related ASHP policies (1208, Transitions of Care, and 1316, Pharmacy Resident and Student Roles in New Practice Models) do not formally address training student pharmacists and residents for roles in transitions of care.

The Council discussed the value of having a designated employee to conduct transitions of care duties within an institution. In general, the Council felt that transitions of care must be multidisciplinary and that follow-up should be handled by the most appropriate members of the health care team (for example, if medications are the focus, then the pharmacist should be responsible; if the issue is wound care, then a nurse should be responsible). The [ASHP-APhA Medication Management in Care Transitions Best Practices](#) document was complimented as important and outstanding work.

Female Executive Pharmacy Leadership

Sheryl Sandberg's book *Lean In* was a suggested (optional) part of the background for this agenda item. Most of the Council members had read the book or were very familiar with it. It was noted that in general the book has generated a great deal of discussion, some negative and some positive.

As part of the discussion, Council members were interested to know whether ASHP has statistics on female pharmacy executives in the workforce, including those in chief pharmacy officer roles. The Council discussed their perception that there are already many women in pharmacy leadership roles, but that gathering accurate statistics on the subject would be important to give this topic appropriate consideration. It was suggested that ASHP collect data.

The Council discussed whether as many female residents were matriculating to top-level positions as their male counterparts. The Council noted that it is well-documented that pharmacists have negligible disparity between genders in salary compared to other professions.

There was consensus that ASHP already has a number of gender-neutral leadership development programs. It was felt that mentorship is an important component of leadership development, and ASHP should continue to encourage mentorship, but that it is often difficult to find a mentor. (The mentor program through the New Practitioner Forum was mentioned.) It may be that the awareness of the availability of leadership training through ASHP needs to be heightened.

There has been an explosion in the number of female pharmacy students. The American Association of Colleges of Pharmacy has a specific program for females in academia to ascend to leadership positions. The number of female leaders in academia has increased over the last ten years, and the number of deans and female department chairs has also grown. The Council felt strongly that ASHP should continue with gender-neutral leadership development and not designate leadership programs specifically for female members.

Valuable Experiences for Student Pharmacists

The Council discussed the New Business Item submitted to the 2013 House of Delegates, “Enhancing the Value of Experiences for Student Pharmacists.” The suggested outcome is the development of policy that supports opportunities to optimize the practice experiences for student pharmacists. As part of the discussion, comparisons to ASHP policies 1110, [Pharmacy Internships](#), and 1316, [Pharmacy Resident and Student Roles in New Practice Models](#), were noted.

The Council discussed differences between states. Some states do not require intern licenses, in which case a pharmacy technician license may be required. It was suggested that it would be ideal if the National Association of Boards of Pharmacy (NABP) promoted consistency related to laws, hours, CE requirements, and licensure across all states to their member boards. There was also discussion about whether having student licenses would actually make experiences for students more meaningful.

The Council examined whether ASHP policies 1316 and 1110 cover the intent of the new business item. The Council agreed that meaningful experiences for student pharmacists are part of the preparation for practice, that having students merely observing or filling a technician role is not desired, and that ASHP should continue to promote valuable experiences. The Council acknowledged that having technician or operational experience is also important and valuable, and that student pharmacists should continue to receive these experiences also. The question of whether a student pharmacist license would actually enhance student experience was posed.

Several Council members cautioned that if ASHP encouraged NABP involvement in standardization of what students or interns are able to do, then it would likely fall to the least common denominator, or the most restrictive, not the optimum. The Council members suggested that the states with issues related to student pharmacist experiences should work through their state affiliates and state boards to advocate for improvements, using existing policy 1316 to support their case. The individual states must work within their systems to create the meaningful opportunities, should barriers exist. In addition, the ASHP student societies should work with their state affiliates and ASHP Student Forum as needed within their state.

The Council discussed whether ASHP should take action beyond policy to help improve student experiences, such as awards, guidance for developing internship programs, stepwise approaches to student experiences, templates, or other resources for student sites. Council members also mentioned sharing innovative models highlighting internship excellence.

Overall, the Council supported the intent of the new business item but decided against creating new policy (including recommending 1204 again) or revising existing policy.

PTCB Certification Program Changes

The recently approved changes to Pharmacy Technician Certification Board (PTCB) certification were reviewed for informational purposes, but also to determine if ASHP needed to take any specific actions. Changes include background checks by 2014, one hour mandatory CE in medication safety, technician-targeted CE only by 2015, and completion of an ASHP-accredited

technician training program by 2020. It was noted that these are required only by PTCB and that individual states may have different approaches to technicians.

The Council discussed planning for the increased need for experiential sites to support more accredited technician training programs. It was felt by many that the experiential sites are already stressed taking pharmacist students. The word needs to get out about the new accredited training program requirement so the profession can begin to plan for it. To achieve this aggressive goal, ASHP needs to be a leader in getting the word disseminated to members and others to ensure an adequate number of sites. The Council strongly encouraged development of a five-year plan to address the need for training sites, including a projection of the number of sites that will be required. The Council encouraged ASHP to find ways to get individuals into accredited training programs. The Council discussed whether a policy or statement should be developed, but ultimately decided it was not necessary.

ACPE Accreditation Standards Revision

The Council was informed that in May 2013 ACPE closed the opportunity to comment on the existing accreditation standards. A draft version of new standards is expected in early 2014, and a formal update is expected in 2015.

The CAPE 2013 Educational Outcomes, fourth revision, was also recently released. The outcomes are created to guide curricular discussions related to curriculum planning, delivery, and assessments within colleges and schools of pharmacy. The theme for change:

1. Continued commitment to science
2. Include an affective domain
3. Write measurable evidence-based outcomes achievable upon graduation
4. Align with other health professions content and language
5. Emphasize pharmacist's unique role
6. Include a preamble and glossary to ensure consistency
7. Find the appropriate balance in outcome detail and minimize redundancy

CAPE contains four broad domains, with fifteen subdomains:

Foundational Knowledge: foundational scientific principles that inform pharmacy practice, permeates all domains; includes integrating science and evaluating scientific literature and applying clinical reasoning.

Essentials for Practice and Care: skill domain identifying what students should know, unique core roles of pharmacists: includes medication use, patient care, and managing health care of transition of care, health and wellness.

Approach to Practice and Care: skill domain identifying how students should perform: including approach to practice, monitoring parameters, educating and assessing understanding, advocacy, and cultural competency.

Personal and Professional Development: this is the new affective domain, identifies the mindset needed for pharmacy practice that brings knowledge and skills together, have

identifies behaviors and attitudes needs that are consistent with other providers; including leadership, innovation and entrepreneurship.

The Council expressed appreciation and support for the CAPE Educational Outcomes 2013 and the work of the CAPE panel members.

Training to Develop C-Suite Leaders

Council members suggested that ASHP consider fostering or developing tools, resources, and education to assist pharmacy leaders move to an executive role within the C-suite.

Technician Leadership Training

As part of the discussion related to the draft *ASHP Statement on the Role of the Pharmacy Technician in Health-System Pharmacy*, it was reported that the ASHP Research and Education Pharmacy Leadership Academy could accept pharmacy technicians, but primarily has been focused on promoting the program only to pharmacists. It was also noted that leadership is an important characteristic no matter what position one may have, although it may be unreasonable to expect that ASHP can teach an individual everything that they need to know.

ASHP Statement on Continuing Education

Next to integrity, competence is the first and most fundamental moral responsibility of all the health professions....Each of our professions must insist that competence will be reinforced through the years of practice. After the degree is conferred, continuing education is society's only real guarantee of the optimal quality of health care.

—Edmund D. Pellegrino

In an era of rapidly accelerating change in health-care delivery, the roles of pharmacy practitioners are being constantly re-defined. As roles change, competency requirements change; and as pharmacy practitioners assume the increased responsibilities demanded in these new roles, they must make a corresponding commitment to improve their professional competence. Continuing education is a means by which practitioners can gain the knowledge and skills necessary to develop, maintain, and improve their professional competence.

In keeping with the mission of the American Society of Health-System Pharmacists (ASHP), the purpose of continuing education for health professionals is the improvement of patient care and health maintenance and the enrichment of health careers. Every practitioner should assume personal responsibility for maintaining and improving professional competence through lifelong, self-directed education. Every pharmacist should set personal educational objectives based on individual needs and career goals. One way to achieve these objectives is through continuing education experiences judiciously selected from among area, regional, and national resources. It should be the role of ASHP to facilitate the efforts of the pharmacist in self-directed education.

Objectives

The objectives for the continuing education services of ASHP shall be

1. To help pharmacists develop a more complete understanding of the importance and methods of lifelong, self-directed education and to encourage and assist them toward this goal.
2. To help practitioners evaluate their professional performance, identify areas where improvement is needed, and set realistic and attainable educational goals.
3. To provide to practitioners information on available area, regional, and national educational resources which will help them achieve their personal educational objectives.
4. To assist pharmacists in selecting educational resources that most effectively fulfill their individual needs.
5. To provide to pharmacists continuing education resources in a variety of formats and media best suited for the

subject matter and needs of the greater number of learners.

Authority

Matters relating to continuing education services will be considered by the Council on Educational Affairs and will be submitted to the Board of Directors for review.

Guidelines

The following guidelines are used in the development and conduct of continuing education programs and activities of ASHP:

1. Continuing education programs will be planned and conducted in accordance with the Criteria for Quality of the Continuing Education Provider Approval Program of the Accreditation Council for Pharmacy Education.
2. ASHP will collaborate, when appropriate, with other professional organizations, agencies, and educational institutions in the planning and conduct of continuing education activities.
3. When appropriate, due consideration will be given to the curricular approach in the planning and implementation of continuing education activities.
4. ASHP may limit or restrict the enrollment for any continuing education program, depending on the nature and requirements of the particular program.
5. ASHP's overall continuing education activity is intended to be self-supporting; however, the benefit versus cost value to members of a specific educational program must also be considered.

This statement was reviewed in 2003 by the Council on Educational Affairs and by the ASHP Board of Directors and was found to still be appropriate.

Approved by the ASHP Board of Directors, November 15, 1989. Developed by the Council on Educational Affairs. Supersedes a previous version approved by the ASHP House of Delegates on May 15, 1978.

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The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

Board of Directors Report on the Council on Pharmacy Management

The Council on Pharmacy Management is concerned with ASHP professional policies related to the process of leading and directing the pharmacy department in hospitals and health systems. Within the Council's purview are (1) development and deployment of resources, (2) fostering cost-effective 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.

Kathleen S. Pawlicki, *Board Liaison*

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Policy Recommendations



A. Pharmacy Department Interface with Business Partners

- 1 To recognize that a key objective of pharmacy departments is to provide
- 2 comprehensive medication management across the continuum of patient care; further,
- 3 To encourage pharmacy leaders to proactively evaluate potential business partnerships
- 4 against this objective; further,
- 5 To recognize that hospitals and health-system pharmacy leaders must ensure that
- 6 business partners meet all applicable patient safety and accountability standards;
- 7 further,
- 8 To provide education and tools for pharmacy leaders to aid in the evaluation of and
- 9 development of business partnerships; further,
- 10 To educate health-system administrators on the importance of pharmacy leadership in
- 11 evaluating and developing pharmacy-related business partnerships; further,
- 12 To encourage health-system pharmacy leaders to consider evolving health care
- 13 financing systems when evaluating and developing business partnerships.

Rationale

Hospitals and health-system pharmacy leaders have to increasingly assess and engage with external business partners in order to facilitate continuity of care for their patients and optimize outcomes. Hospitals and health-system leaders must be positioned to provide the most comprehensive care for their patient populations. As these external entities expand their market share and become more engaged across the health care continuum, a significant number of hospitals and health systems are dealing with how to best evaluate potential business partnerships. In some cases hospital or health-system pharmacy leaders are seeking to create a network of pharmacy locations and services for their patients that the health system cannot build itself. In other cases hospital and health-system pharmacy leaders need to engage with external business partners to provide services they cannot provide or to improve the efficiency of services provided by the hospital or health system. Additionally, a number of business entities see changes in value-based purchasing and readmission payment as an opportunity to contract with health systems. Finally, there are also business partners (e.g., data management, automation, compounding, and consulting organizations) that pharmacy leaders need to engage with in order to manage their pharmacy enterprise. These changes have posed a political, logistical, and professional challenge for pharmacy leaders.

Background

The Council voted and the Board agreed that ASHP should establish policy on pharmacy-related business partnerships as they increasingly become part of hospital and health-system pharmacy leaders' management and monitoring responsibility in meeting the demands of the Patient Protection and Affordable Care Act. The Council discussed the impact of the Affordable Care Act requirement that the Center for Medicare & Medicaid Services (CMS) reduce payments to hospitals with high 30-day readmission rates for three conditions (heart failure, heart attack, and pneumonia), as well as the resulting development of accountable care organizations (ACOs) and integrated delivery networks. Section 3025 of the Affordable Care Act added section 1886(q) to the Social Security Act, which requires CMS to reduce payments to Inpatient Prospective Payment System hospitals with high rates of readmission. With CMS focusing on hospital readmission rates as a major performance indicator and with almost 20 percent of patients discharged from hospitals being readmitted within 30 days, CMS estimates the cost to be approximately \$12 billion per year. Reducing readmissions can help CMS save significantly while improving patient outcomes. The penalties are capped at 1% of Medicare reimbursements in 2013, with increases to 2% in 2014 and 3% in 2015.

Newly created external liaison programs offered by community pharmacies (e.g., Walgreens' WellTransitions and CVS Caremark's partnership with Dovetail Health) have as their primary goals reducing preventable hospital admissions and improving health outcomes. Additionally, hospital and health-system pharmacies are increasingly called upon to coordinate patient care with specialty pharmacy services when patients require admission.

The Council discussed the opportunities and challenges for hospitals and health systems in expanding continuity of patient care in light of the expanding role of these new entities. The Council also discussed what elements should be in policies or guidelines for evaluating the benefits and challenges of potential business partnerships with these organizations. Additionally, the Council discussed how these changes allow health-system pharmacists to expand their practice further into the ambulatory care practice setting.

The Council noted that these pharmacy-related business partnerships will increasingly become part of hospital and health-system pharmacy leaders' management and monitoring responsibility. It will be important for ASHP to provide education and resources for practitioners to help ensure they are equipped to ensure that the outcomes of these partnerships meet their organizations' missions and standards.



B. Integration of Pharmacy Services in Multifacility Health Systems

- 1 To advocate that pharmacists are responsible for organizational efforts to standardize
- 2 and integrate pharmacy services throughout the entire pharmacy enterprise in
- 3 multifacility health systems and integrated delivery networks; further,

- 4 To educate health-system administrators about the importance of pharmacy leadership
- 5 in setting system-wide policy regarding the safe and effective use of medications;
- 6 further,

- 7 To advocate for the regulations and resources needed to support efforts to achieve
- 8 optimal patient health outcomes in multifacility organizations.

(Note: This policy would supersede ASHP policy 1210.)

Rationale

Data from a 2011 American Hospital Association annual survey of hospitals indicate that at the time of the survey, 4432 of 5724 hospitals were part of either a system or a network, reflecting the evolution of the health care enterprise from single hospitals to integrated systems and networks. Multiple hospitals organized and owned by the same system have been in the United States marketplace for decades, but the rapidly changing marketplace in the past 2–3 years seems to foreshadow a future in which every hospital in the country will be part of a system. These systems have become increasingly complex as they also delve into non-hospital based businesses and seek to standardize and gain economies of scale across the organization.

These new organizations and the recognition of the importance of medication management to the overall health of these organizations have led to new roles and new challenges for pharmacy leaders. The pharmacy enterprise of the future will be more sophisticated and corporate in its nature. Pharmacy leaders both at the local hospital and at the corporate level have to more so than ever look at their pharmacy services in the context of the overall goals and needs of the organization or health system and determine the most efficient and effective means to provide these services. Leadership of the pharmacy must evolve from a department leader in a single facility to an effective corporate leader of medication use across a wide array of business units, care settings, and organizations. Centralization of medication management services is no longer confined to drug distribution but also includes human resources management, integrity of the electronic health record and related patient-care information, and oversight of various business partners. Pharmacy leaders within these evolving health systems will have many challenges, ranging from communication among the pharmacy management team, decisions on pharmacy infrastructure purchases and contracting, identification of critical services and standardization, succession planning and workforce development, supply chain management, human resource coordination, and strategic planning across diverse hospitals within the system.

Further challenging health system pharmacy leaders are coordinating pharmacy services across larger geographical regions.

The nature and culture of decision making will be changed as some decisions become more centralized and corporatized and new practice models are developed to capitalize and adapt to the changing market place. Especially as merged systems extend beyond local and regional markets, health care will likely become even more business-like in its decision-making and fewer decisions will be made at the local facility level. The pharmacy enterprise will need to adapt to this changing environment. Many important decisions that influence medication-use policy will be made at the level of corporate leadership, and it will be critical that pharmacists provide leadership in this corporate decision-making. The ability to demonstrate the financial impact of pharmacy services will be critical and the development and implementation of effective drug-use policy across the enterprise will be crucial to success.

Along with increasing consolidation and integration of health systems, the business model for health care is also evolving. Pharmacy leaders will need to become familiar with changing business imperatives and align the pharmacy business plan with that of the health system. Planning must integrate at both the strategic and tactical level. Pharmacy needs to be envisioned as a service rather than a department. These changes have resulted in the need to evaluate best practices, legal and regulatory requirements, and leadership structure.

Background

The Council voted and the Board agreed to recommend amending policy 1210, Role of Corporate Pharmacist Leadership in Multifacility Organizations, as follows:

To advocate that ~~a~~ pharmacists ~~must be~~ are responsible for ~~leadership and have responsibility for standardization and integration of~~ organizational efforts to standardize and integrate pharmacy services ~~in multiple business units across throughout~~ the entire pharmacy enterprise ~~in~~ of multifacility health systems and integrated delivery networks; further,

To educate health-system administrators about the importance of pharmacy leadership in setting system-wide policy regarding the safe and effective use of medications; further,

To advocate for the regulations and resources needed to support efforts to achieve optimal patient health outcomes in multifacility organizations.

The Council discussed the need for policy to address the complexities of leading medication management services for multifacility organizations and the need for supporting rules, regulations, and resources necessary to facilitate the evolving needs in health care. The Council suggested that ASHP will need to study the regulatory and legal enablers and barriers that exist as pharmacy leaders seek to build the best practice models in these large complex organizations. ASHP policy will need to be assessed along with ASHP's member resources, public relations, and advocacy efforts.



C. Risk Assessment of Health Information Technology

- 1 To urge hospitals and health systems to perform appropriate risk assessment before
- 2 new health information technology (HIT) is implemented or existing HIT is upgraded;
- 3 further,
- 4 To advocate that HIT vendors provide estimates of the resources required to implement
- 5 and support new HIT; further,
- 6 To collaborate with HIT vendors to encourage the development of HIT that improves
- 7 patient-care outcomes.

Rationale

The adoption of HIT in hospitals has been increasing at a quickening pace. The ASHP National Survey – 2012 reports the adoption of the following: full paperless electronic health record (EHR) (18.6%), computerized provider order entry with clinical decision support (CPOE with CDS) (54.4%), bar-coded medication administration (BCMA) (65.5%), and smart pumps (77%). The adoption of HIT has undoubtedly been spurred by the American Recovery and Reinvestment Act (ARRA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions under Meaningful Use (MU) of the EHR. Hospitals have been incentivized to implement EHRs that meet the MU criteria by increased reimbursement through Medicare and/or Medicaid payments. Due to the strict guidelines and the rush to meet incentive payments, many providers are questioning whether some HIT is being implemented too quickly.

The implementation of HIT within the medication-use process has been proven to prevent and decrease errors, improve quality, and prevent waste. A key premise of the Office of the National Coordinator for Health Information Technology (ONC) report “Health Information Technology Patient Safety Action & Surveillance Plan” (July 2013) is that HIT, when fully integrated into health care delivery organizations, facilitates substantial improvements in health care quality and safety as compared to paper records. As hospitals and providers implement HIT within their institutions and practices, however, they often encounter new types of errors and problems. The medical literature is starting to see reports of these unintended consequences of HIT, so continuous monitoring of these systems is required. It has become increasingly important to properly assess the interface between HIT and users to identify whether any new risk has been introduced to the system and implement HIT appropriately, taking into account medication-use processes and human factors. Critical questions hospitals and health systems face include (1) when do HIT advances exceed the capacity for integration into workflow, (2) when does HIT begin to introduce risk into the medication-use process rather than improve patient safety, and (3) what are the accountabilities of HIT providers, regulators, and providers to ensure the necessary product development and assessments are made before implementation of new HIT.

ASHP advocates that a pharmacist be part of the implementation team for any medication-related technology within an institution. Technology assessment tools should be applied to proactively determine gaps in function prior to implementation. The use of failure modes effects analysis (FMEA) and other resources should be considered. Risk assessment should also be considered when implementing any new technology to ensure that unintended consequences are minimized.

Regulatory and accreditation organizations include components of risk assessment and quality improvement within their criteria, but hospitals need to incorporate these into their overall plans. Such risk assessments could result in less attention on some HIT implementations.

Background

The Council voted and the Board agreed that ASHP should establish policy on pharmacist-led risk assessment of all new medication-use technologies implemented in hospitals and associated clinics. This discussion included reviewing whether appropriate attention is placed on technology implementation and its impact on current, present, and future pharmacy workflows whether ASHP has any recommendations on how to conduct a risk assessment for implementing new medication use technologies, and whether there is sufficient oversight by regulatory and accrediting organizations on institutions implementing medication-use technologies.



D. Documentation of Patient-Care Services in the Permanent Health Record

- 1 To advocate for public and organizational policies that support pharmacist
- 2 documentation of patient-care services in the permanent patient health record to
- 3 ensure accurate and complete documentation of the care provided to patients and to
- 4 validate the impact of pharmacist patient care on patient outcomes and total cost of
- 5 care; further,
- 6 To advocate that electronic health records be designed to accommodate
- 7 documentation by pharmacists.

(Note: This policy would supersede ASHP policy 0407.)

Rationale

Documentation in the patient record is a critical for a complete record for patient care and communication among members of the health care team. The documentation should be done within an electronic health record (EHR) or on paper. When documenting electronically, the use of standardized and coded formats will allow for improved outcome measurements by pharmacists.

Background

The Council discussed as part of its sunset review policy 0407, Documentation of Pharmacist Patient Care Services, which reads:

To encourage the documentation of pharmacist patient care services in order to validate their impact on patient outcomes and total cost of care.

The Council concluded that the existing policy did not state strongly enough the need for pharmacist documentation in the patient record and did not express the important corresponding accountabilities associated with such documentation. The Council voted and the Board agreed that ASHP’s policy should be strengthened and updated to recognize EHRs. The ASHP Pharmacy Practice Model Initiative (PPMI) was reviewed and it was decided that PPMI recommendations should be incorporated into an updated and revised policy. The Council voted and the Board agreed to recommend changes to the policy language as follows:

To ~~encourage the documentation of pharmacist patient care services in order~~ advocate for public and organizational policies that support pharmacist documentation of patient-care services in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and ~~to validate their impact of pharmacist patient care~~ on patient outcomes and total cost of care; further,

To advocate that electronic health records be designed to accommodate documentation by pharmacists.



E. Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient-Assistance Programs

- 1 To encourage pharmaceutical manufacturers to extend their patient assistance
- 2 programs (PAPs) to serve the needs of both uninsured and underinsured patients;
- 3 further,

- 4 To advocate that pharmaceutical manufacturers and PAP administrators enhance
- 5 access to and availability of such programs by standardizing application criteria,
- 6 processes, and forms, and by automating PAP application processes through
- 7 computerized programs, including Web-based models; further,

- 8 To advocate expansion of PAPs to include high-cost drugs used in inpatient settings;
- 9 further,

- 10 To encourage pharmacists and pharmaceutical manufacturers to work cooperatively to
- 11 ensure that essential elements of pharmacist patient care are included in these
- 12 programs.

(Note: This policy would supersede ASHP policies 0404 and 9703.)

Background

As part of sunset review, the Council discussed ASHP policy 0404, Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient-Assistance Programs, which reads:

To advocate standardization of application criteria, processes, and forms for manufacturer-sponsored patient assistance programs (PAP); further,

To advocate the automation of PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drugs used in inpatient settings.

The Council concluded the issue is still important and ASHP should have policy on the topic. The Council also reviewed policy 9703, Manufacturer-Sponsored Patient-Assistance Programs, which reads:

To encourage pharmaceutical manufacturers to (1) extend their patient assistance programs to serve the needs of both uninsured and underinsured patients, (2) enhance access to and availability of such programs, and (3) incorporate the elements of pharmaceutical care into these programs.

The Council voted and the Board agreed these policies were both important and needed, but that they should be combined into a single policy.



F. Fostering Pharmacy Leadership

To discontinue ASHP policy 9901, which reads:

- 1 To encourage pharmacy managers to serve as mentors to their staff, pharmacy
- 2 students, pharmacy residents, and peers in a manner that fosters the development of
- 3 future pharmacy leaders.

Background

As part of sunset review, the Council reviewed policy 9901. Although the policy was considered to still be relevant and important, the Council concluded that the policy was redundant with ASHP policy 0509, Developing Leadership and Management Competencies, which reads:

To work with health-system leadership to foster opportunities for pharmacy practitioners to move into pharmacy leadership roles; further,

To encourage current leaders to seek out and mentor practitioners in developing administrative, managerial, and leadership skills; further,

To encourage interested practitioners to obtain the skills necessary to pursue administrative, managerial, and leadership roles; further,

To encourage colleges of pharmacy and state affiliates to foster leadership skills in students through development and enhancement of curricula, leadership conferences, and other programs; further,

To encourage colleges of pharmacy to develop more opportunities for students to pursue combined degree programs; further,

To encourage colleges of pharmacy and health systems to develop more opportunities for students to pursue residency programs that develop administrative, management, and leadership skills; further,

To encourage residency programs to develop leadership skills by mentoring, training, and providing leadership opportunities; further,

To encourage residency programs to provide training for residents to develop administrative and management skills; further,

To foster leadership skills for pharmacists to use on a daily basis in their roles as leaders in medication safety and medication management in patient care.

The Council and Board agreed that the language of policy 9901 was similar to that in policy 0509 and therefore there was no longer a need for policy 9901.

Board Actions

Sunset Review of Professional Policies

As part of sunset review of existing ASHP policies, 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.)

- [Workload Monitoring and Reporting](#) (0901)
- [Pharmacist Leadership of the Pharmacy Department](#) (0918)
- [Intimidating or Disruptive Behaviors](#) (0919)
- [Standardized Clinical Drug Nomenclature](#) (0920)
- [Pharmacy Drug Theft](#) (0303)
- [Optimizing the Medication-Use Process](#) (9903)
- [ASHP Guidelines on Outsourcing Pharmaceutical Services](#)

Other Council Activity

Pharmacy-Sensitive Measures and Metrics

The Council voted to explore the potential benefits of convening a member expert panel to advise ASHP on the following areas: (1) the utility of an pharmacy-sensitive database that would collect pharmacy data that would supplement and support the demonstration of pharmacy outcomes, (2) a needs assessment on types and level of resources and education for pharmacy leaders in managing data to demonstrate pharmacy outcomes, (3) the adoption and application of the proposed pharmacy sensitive quality measures identified by the ASHP workgroup, and (4) the integration of the complexity index research forthcoming from the ASHP Foundation.

Workload and productivity measures that effectively assess the outcomes of pharmacists and pharmacy service continue to be a significant concern for ASHP members. Additionally, the pressures on the health care system to correlate workload with outcomes through quality measures is a challenge facing all health care providers, resulting in heightened concern by pharmacy leaders for the need for pharmacy-sensitive measures. The Council discussed ASHP policy related to health care quality measures and performance improvement metrics and their relationship to acuity of medication therapy.

The Council addressed a number of issues, including: (1) Does ASHP have sufficient policy on quality measures, performance metrics, outcomes, and medication therapy acuity? (2) How does the patient's health status affect the productivity of health-system pharmacists, and what aspects are controllable? (3) Where do productivity, patient acuity, and health outcomes converge and diverge? (4) How do pharmacy workload and productivity measures relate to health care quality measures? (5) How do acuity measures contribute to workload and productivity of the pharmacy?

The Council concluded that workload and productivity measures in and of themselves cannot be relied upon to support or defend any one particular practice model and that a combination of dashboards, outcomes data collection, integration with health-system objectives, and communication most effectively expresses the work and efforts of a pharmacy service. The Council acknowledged that in the current environment pharmacy leaders were continually struggling in debating the merit of traditional workload and productivity measures used by consultants and for budgeting. The Council also recognized the need for evidenced-based complexity tools to aid in decision-making on how to best manage resource allocation and for better profession-wide data sets that incorporate factors that affect pharmacy workload not currently present in hospital-level case-mix indices.

The Council reviewed ASHP publications and policies on workload, productivity, and quality measures. The Council concluded the current policies were adequate and did not require amendment. Additionally, the Council reviewed the work of the ASHP workgroup that has been charged with identifying existing quality measures for medication-related preventable harm that can be impacted by pharmacy.

The Council took into consideration during their discussion the following information and activities. In "Method to determine allocation of clinical pharmacist resources" by Granko et al., the authors describe an objective method to identify the highest-risk patients for clinical pharmacy resource allocation. They concluded that a validated tool was lacking and developed a novel pharmacy-staffing tool to allocate clinical pharmacy staff among hospital departments. This tool

used a combination of census, patient acuity measured by a proprietary algorithm based on MS-DRGs, teaching involvement, medication costs, and use of high-priority medications. The tool confirmed current staffing assignments and is used on an annual basis to support staffing requests. Patient acuity has a large influence on clinical outcomes, and preliminary assessments can aid in distributing resources. The ASHP Foundation is currently funding a two-year grant to develop a medication complexity index with the goal of creating a tool to efficiently assess patients that require more focused attention to medication management. Patient experience of care also plays an important role in quality of care. A three-item care transition measure has been incorporated in the Hospital Consumer Assessment of Healthcare Providers Survey (HCAHPS). Two of the questions (“When I left the hospital, I clearly understood the purpose of taking each of my medications.” and “When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.”) directly incorporate the patient’s understanding of medication therapy at the point of discharge. In “Effective use of workload and productivity monitoring tools in health-system pharmacy” parts one and two by Rough et al., the authors look toward standardizing and identifying productivity metrics for hospital pharmacy. The authors describe several pitfalls, barriers, and strategies for evaluating productivity and workload in health-system pharmacy and provide guidance on internal benchmarking. They also acknowledge the current lack of broad, standardized, and validated tools for use in allocating resources and understanding efficiency.

Expansion and Management of 340B Program Within Health Systems

The expansion of the 340B Drug Pricing Program has come under significant scrutiny in the last two years while the number of 340B-qualified and participating hospitals has more than doubled. The expectation that hospital and health-system leadership will engage with the 340B program when possible has challenged pharmacy leaders, especially with the newly enforced group purchasing organization (GPO) exclusion rules and the acquisition of many off-campus clinics. Additionally, there is significant opposition to and scrutiny of the number of hospitals utilizing the 340B program and how the program is being implemented, which will require pharmacy leaders to carefully lead their organizations.

The 340B Drug Pricing Program was enacted in 1992 to allow hospitals and other “covered entities” to better serve larger numbers of indigent and underserved patients, and also to allow these entities to stretch their federal resources to reach eligible patients. Congress has expanded the program since its inception to include additional safety net hospitals. Additionally, the program has changed from allowing a participating entity to contract with just one pharmacy to dispense 340B medications to allowing multiple contract pharmacy arrangements.

Between 2001 and 2011, the number of covered entity sites participating in the 340B program almost doubled, from 8,605 to 16,572. A search of the Office of Pharmacy Affairs (OPA) Database (<http://opanet.hrsa.gov/opa/CESearch.aspx>) performed on August 7, 2013, found that there are currently a total of 22,634 covered entity sites participating in the 340B program, and 38,350 contract pharmacy arrangements. The significant growth of the program is due, in part, to 340B-eligible hospitals continuing to acquire ambulatory clinics, and the recent legislative changes that allow more hospitals to qualify for the program.

Additionally, the number of 340B-eligible entities is expected to increase further when more low-income individuals become eligible under Medicaid due to provisions contained in the

Patient Protection and Affordable Care Act (ACA). However, it is interesting to note that, according to a recent letter to the *Wall Street Journal* by the American Hospital Association, drugs that are purchased through the 340B program represent only 2% of the total drugs purchased in this country.

In a September 2011 Government Accountability Office (GAO) report on the 340B program, the GAO noted a lack of oversight by the Health Resources and Services Administration (HRSA) over the program. Additionally, the GAO was concerned that the increasing number of contract pharmacy arrangements would result in a greater risk of diversion. Since that time, the Office of Pharmacy Affairs has conducted audits and published their findings on the OPA Web site (<http://www.hrsa.gov/opa/programintegrity/auditresults/auditreport071213.pdf>). Congressional inquiries have also been initiated regarding the use of 340B savings by certain hospitals, and most recently, Senator Grassley sent a letter to Walgreens requesting information about their involvement with the program, stating that “The intent and design of the program is to help lower outpatient drug prices for the uninsured. It is not intended to subsidize pharmacies that team up with covered entities to turn a profit.”

In this environment, hospitals and health systems need to be aware of the risks and benefits of further expanding into the 340B program. An overall benefit of the program is the provision of better continuity of care and transitions of care as 340B-covered entities provide underserved patients with greater access to the medications and services they need due to the cost savings that hospitals realize through the program.

The Council discussed the benefits of the 340B program, which include (1) the offset of losses that result from providing free or below-cost pharmacy services, (2) the ability to provide free or less-expensive medications to patients, (3) the establishment of medication-use programs for patients, (4) expanding access to more expensive medications, and (5) the ability to care for larger numbers of patients. The Council also discussed the risks facing the 340B program if proper management and compliance were not maintained, including (1) perception of lack of program integrity, (2) government audits, and (3) diversion of 340B drugs to individuals who are not patients of the covered entity. Additionally, the Council discussed the growing need among hospital and health-system pharmacy leaders for tools and resources to support compliance and management of the 340B program. The Council’s policy recommendations were incorporated into the Council on Public Policy’s policy recommendations to update and amend ASHP policy 0506 and included addressing the critical need of the 340B program to meet patient needs, recognition of health-system partners to help support compliance requirements, the impact on resource needs to manage the program, and the importance of appropriate stewardship of the 340B program.

Pharmacist Responsibility, Accountability, and Liability with EHR Documentation and Verification

The introduction of electronic health records (EHR) has improved access to and continuity of patient information in health care. As with the introduction and expansion of any new technology, assessing the intended and unintended outcomes of implementation is critical for the safe and consistent utilization of the tools and resources. The Council discussed the impact of the EHR and its interface with computerized physician order entry, pharmacy systems (integrated and nonintegrated), pharmacist review and management of medication and related patient data, and how pharmacist information is managed within these systems. Also discussed were the new and

different ways pharmacy managers and leaders can assess the efficiencies and effectiveness of their pharmacy personnel as they manage their patients and associated workload.

The review and verification of medication orders within a computerized provider order entry (CPOE) environment allows for timely review of medication orders. Since this review can be done without transcription of the medication order into a pharmacy information system, the pharmacist may assume that specific screening and choices have been made by the prescriber. This may or may not be true based on the configuration of the CPOE system. Some institutions may have configured the alerts (Drug-Drug Interactions [DDI], Drug Allergy, Dose Range Checking [DRC], duplicate, and other alerts) differently, based on the provider. Some institutions may not present duplicate checking for prescribers, but require it for the pharmacist upon order verification. The level of DDI may be set at severe contraindication for prescribers, but it may include all interactions for the pharmacist verification. Many hospitals build specific alerts for guiding prescribers in meeting guidelines and other best practices. Ensuring that the pharmacist is aware of these guidelines during order verification is essential to ensure appropriate therapies for the patient. The problem with alert fatigue should be considered when incorporating medication-related alerts in any CPOE system. The systematic review and fine-tuning of alerts should be conducted on a frequent basis to evaluate for timing, frequency, sensitivity, and compliance with the alert. When reviewing the alert data/history, a committee should be instituted to deal with all forms of clinical decision support (CDS) governance. This could include review and approval of new alerts, review and approval of order sets and sentences, and development of metrics for CDS success within a given institution.

The Council concluded the review and management of medication orders electronically from an accountability and liability standpoint is no different than the review and management of medication orders from a written order and pharmacist's documentation in the paper medical record. The Council did note that with the expansion of the EHR it would be important to ensure the necessary infrastructure for pharmacists be established, such as ability to document in areas of the EHR as other health care providers when documenting their outcomes. Additionally, it would be important the necessary information is accessible, processes and work flows evaluated, data management and prioritization processes established, and best practices identified on pharmacists documentation and process management.

Oversight of Medication Use and Management Standards in Remote and Off-Campus Facilities

The combination of hospitals and health systems establishing and acquiring off-campus patient-care services (i.e., medical offices, infusion centers, and ambulatory surgical centers), the utilization of telehealth to provide expanded access, and the goals of providing expanded and/or 24-hour medication management services to hospitals has created challenges for hospital and health-system leaders in ensuring safe and comprehensive medication management services are provided that have appropriate oversight and meet regulatory standards. The Council discussed the growth of remotely-provided health care in the United States and the increasing number of facilities that are significantly geographically distant from the responsible health-system pharmacy or pharmacist in charge. Additionally, with the ability to have health care providers in any location while providing patient care it has become important to ensure the integrity of patient

information is maintained and that the health care provider's work environment is conducive to safely providing patient care.

The Council discussed the growing number of settings in which pharmacists are expected to have oversight and medication management services are needed or required. The Council's discussion included situations where hospital medication management regulatory requirements were expected to be enforced in affiliated organizations and where associated hospitals may not have significant pharmacist presence.

As the new health care landscape continues to evolve and there is a heightened demand for increased health care access, increased coordination among health-system-owned entities, and increased implementation of telehealth and its various forms (telemedicine, telepsychiatry, telepharmacy, etc.), caring for patients remotely has been propelled from considerations to realizations. Although the innovative use of communication and technology to treat patients has become an integral part of health care, ensuring quality and safety in the delivery of health care through this means remains a challenge. It was noted that from a pharmacy perspective, telepharmacy affords the profession a unique opportunity to leverage technology to demonstrate the inherent value, as well as the important skills, pharmacists bring to the health care team. Additionally, telepharmacy represents an innovative way to deliver pharmacy services to rural, frontier, and/or other medically underserved areas using information and communication technology to incorporate the safe practices of the traditional mode of delivery.

The Council also discussed the continued need by pharmacy practice leaders to educate hospital executives on the complexities of indirect and direct accountabilities of pharmacists-in-charge (PICs) concerning medication management and the important roles and responsibilities PICs have in their organizations. The Council believed that pharmacists in general did not have a clear understanding of the scope of accountabilities of the PIC role in the current health-system practice setting, and that ASHP should conduct research on the state laws and regulations regarding liability and provide education on the liability and risk associated with PIC roles. The Council felt it was important for health-system pharmacy to continually assert that in all health care settings every patient deserves optimal medication management. The Council emphasized that pharmacist oversight is necessary to ensure that laws, rules, regulations, standards, and best practices for medication management are implemented and enforced in all patient-care settings where medications are administered or stored. The Council added that appropriate support must be available for use of technology, staff, and resources to facilitate medication management in offsite or remote patient-care locations, and that in all locations where patient-care information is managed the resources, tools, and environment needed to ensure to maintain patient privacy and safe care are available. The Council suggested that ASHP provide a compilation document of policies related to small and rural hospital pharmacy services, remote order entry, and telepharmacy for use in educating health-system leaders and as a resource for health-system pharmacists.

ASHP Statements and Guidelines

The Council reviewed the outstanding statement and guidelines proposals. The outstanding statement and guidelines proposals were provided to the Council with the prioritization information completed by the Council. The Council discussed the process and resources needed to accomplish the completion of these documents and developed a plan to accomplish their goals

over the next year. Additionally, the Council decided to remove the proposed guidelines related to pharmacist privileging and credentialing in hospital and health systems, effective use of consultants within the pharmacy enterprise, and emergency planning. The Council made these decisions based on information that these areas had been addressed through other education and resources for members.

As a result of sunset review, the Council voted to revise the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive to take into account the new and emerging roles of the pharmacy executive with the expansion of multifacility health systems; to revise the ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems to address PPMI recommendations; and to revise the ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems to include the most current cost management strategies and address issues related to population health cost management strategies.

The Council also reviewed the draft *ASHP Statement on the Role of Pharmacy Technicians in Health System Pharmacy Practice* prepared by the Section of Inpatient Care Practitioners and made suggestions on how the document could be strengthened. The suggestions were shared with the drafters.



The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics

Position

1 The American Society of Health-System Pharmacists (ASHP) believes that pharmacogenomic
2 testing can improve medication-related outcomes across the continuum of care in all health-
3 system practice settings. These improvements include reduction in suboptimal clinical
4 outcomes, decreased cost of treatment, better medication adherence, more appropriate
5 selection of therapeutic agents, decreased length of treatment, and enhanced patient safety.¹⁻³
6 Because of their distinct knowledge, skills, and abilities, pharmacists are uniquely positioned to
7 lead inter-professional efforts to develop processes for ordering pharmacogenomic tests and
8 for reporting and interpreting test results. They are also uniquely qualified to lead efforts to
9 guide optimal drug selection and drug dosing based on those results. Pharmacists therefore
10 have a fundamental responsibility to ensure that pharmacogenomic testing is performed when
11 needed and that the results are used to optimize medication therapy.¹ Pursuant to this
12 leadership role, pharmacists share accountability with other hospital and health-system
13 leaders, such as physicians, laboratory professionals, and genetic counselors, for the ongoing
14 implementation and application of pharmacogenomics across the continuum of care. Because
15 test results will have implications throughout a patient's lifetime, all pharmacists should have a
16 basic understanding of pharmacogenomics in order to provide appropriate patient-care
17 recommendations. Some advanced pharmacist functions in applying clinical pharmacogenomics
18 may require specialized education, training, or experience. ASHP encourages pharmacist
19 education on the use of pharmacogenomics and advocates inclusion of pharmacogenomics and
20 its application to the therapeutic decision-making process in college of pharmacy curricula and
21 Board of Pharmacy Specialties certification programs.

Background

22 Clinical pharmacogenomics uses genetic information to guide optimal drug selection and drug
23 dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity.²

24 Pharmacogenomic testing can be performed reactively or preemptively. Reactive testing
25 generally occurs when a patient is experiencing adverse effects unexplained by dose or drug-
26 drug or drug-disease interactions, or when the use of a high-risk drug is anticipated and the
27 patient's genotype is obtained in anticipation of starting therapy. In contrast, preemptive
28 testing occurs when patients are screened for multiple pharmacogenomic variants prior to
29 developing an indication for specific pharmacotherapy.

30 Application of pharmacogenomic information requires an understanding of how genetic
31 variations impact the pharmacokinetic and pharmacodynamic properties of a drug in specific
32 diseases and patient populations, as well as understanding molecular pathways. The influence
33 of factors such as age, sex, diet, pathophysiologic conditions, and current medication use, as
34 well as their relationship to genetic variability must also be understood. As awareness of
35 individual genetic variation grows due to improved access to lower-cost testing and availability
36 of evidence-based consensus guidelines in pharmacogenomics,⁴ the development of patient-
37 individualized therapeutic regimens should include an assessment of patients'
38 pharmacogenomic profiles in addition to allergy and adverse reaction history, drug interactions,
39 dietary and lifestyle factors, patterns of adherence, and other therapeutic drug-monitoring
40 parameters.⁵ The FDA provides a list of drugs for which pharmacogenomic markers are included
41 in the drug labeling,⁶ and the Clinical Pharmacogenetics Implementation Consortium (CPIC) has
42 published ASHP-endorsed therapeutic guidelines for multiple drug-gene pairs.^{7,8}

43 The pharmacist's patient-care functions include appropriate and cost-conscious
44 medication selection and monitoring, which now increasingly includes pharmacogenomic
45 profile assessment. The purpose of this statement is to describe pharmacists' responsibilities
46 and accountabilities in the field of pharmacogenomics.

Pharmacists' Responsibilities

47 Pharmacists' responsibilities for pharmacogenomics include promoting the optimal use and
48 timing of pharmacogenomic tests; interpreting clinical pharmacogenomic test results; and
49 educating other pharmacists, fellow health care professionals, patients, and the public about
50 the field of pharmacogenomics. The following are responsibilities that should be part of any
51 clinical pharmacogenomics service:

- 52 • Advocating for the rational and routine use of pharmacogenomic testing.
- 53 • Providing test result interpretation and clinical guidance for return of results to
54 providers and patients in collaboration with other health care professionals (e.g.,
55 physicians, laboratory professionals, and genetic counselors).
- 56 • Optimizing medication therapy based on pharmacogenomic test results.
- 57 • Educating and providing information on the clinical application of pharmacogenomics to
58 health professionals, patients, and members of the public.

- 59
- Supporting and participating in research, consortia, and networks that guide and
- 60 accelerate the application of pharmacogenomics to clinical practice.

61 Using these responsibilities as a guide, ASHP has developed the following recommendations for
62 pharmacists' functions in pharmacogenomics.

Pharmacists' Functions

63 A pharmacist's functions in clinical pharmacogenomics will vary, depending on education,
64 training, experience, and the needs of the practice setting. All pharmacists should have a basic
65 understanding of pharmacogenomics in order to provide patient care that incorporates
66 pharmacogenomic recommendations. Elements of a basic understanding of pharmacogenomics
67 should enable pharmacists to perform the following functions:

- 68 • Recommending or scheduling pharmacogenomic testing to aid in the process of drug
69 and dosage selection.
- 70 • Designing a patient-specific drug and dosage regimen based on the patient's
71 pharmacogenomic profile that also considers the pharmacokinetic and
72 pharmacodynamic properties of the drug. These factors should be combined in the
73 regimen design along with other pertinent patient-specific factors such as comorbidities,
74 other drug therapy, demographics, and laboratory data to optimize patient outcomes.
- 75 • Educating patients, pharmacists, and other health care professionals about
76 pharmacogenomic principles and appropriate indications for clinical pharmacogenomic
77 testing, including the cost-effective use of pharmacogenomic testing.⁹
- 78 • Communicating pharmacogenomic-specific drug therapy recommendations to the
79 health care team, including documentation of interpretation of results in the patient's
80 health record.¹⁰

81 Pharmacists with specialized education, training, or experience in pharmacogenomics should
82 also assume the following additional functions:

- 83 • Developing pharmacogenomic-specific clinical decision support tools in electronic health
84 record systems that guide prescribers on the appropriate use and dosing of medicines
85 based on a patient's pharmacogenomic profile.¹¹⁻¹³
- 86 • Developing a process, including patient-specific educational materials, to explain to
87 patients the importance and significance of their pharmacogenomic test results, not
88 only in the short term but also over the patient's lifetime.
- 89 • Developing institutional guidelines and processes for implementation of a clinical
90 pharmacogenomic service.

- 91 • Establishing a process for communicating patient-specific results, including
92 documentation of the results in the patient's health record.
- 93 • Establishing a mechanism for revisable reporting (re-interpretation of findings based on
94 evolving science) over the course of the patient's care with the institution and beyond.
- 95 • Developing processes to document improved patient outcomes and economic benefits
96 resulting from clinical pharmacogenomics.
- 97 • Serving as an expert consultant on a clinical pharmacogenomics service.
- 98 • Contributing to the evaluation and implementation of clinical pharmacogenomic testing
99 as an integral part of medication therapy.
- 100 • Promoting collaborative relationships with other health care professionals and
101 departments involved in drug therapy to encourage the development and appropriate
102 use of pharmacogenomic principles in patient care.
- 103 • Applying collaborative drug therapy management principles to a clinical
104 pharmacogenomics service, including advocating for the reimbursement of
105 pharmacogenomic tests and pharmacist interpretation by health insurance plans.
- 106 • Developing and planning pharmacogenomic-specific advanced training opportunities for
107 pharmacists and other health care professionals.
- 108 • Actively contributing to the body of knowledge in pharmacogenomics by publishing
109 articles on the topic in the biomedical literature.
- 110 • Designing and conducting pharmacogenomic research.

Conclusion

111 ASHP believes that pharmacists have a responsibility to take a prominent role in the clinical
112 application of pharmacogenomics. This emerging science should be spearheaded in many
113 institutions by pharmacists to promote safe, effective, and cost-efficient medication practices.

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Governing Documents of the American Society of Health-System Pharmacists

ASHP CHARTER

First. The undersigned, whose names and post office addresses are set forth at the end of this document, each being at least 18 years of age, do hereby form a corporation under the general laws of the state of Maryland.

Second. The name of the corporation is American Society of Health-System Pharmacists, Inc. (ASHP).

Third. The purposes for which ASHP is formed are as follows:

1. To advance public health by promoting the professional interests of pharmacists practicing in hospitals and other organized health care settings through:
 - a. Fostering pharmaceutical services aimed at drug-use control and rational drug therapy.
 - b. Developing professional standards for pharmaceutical services.
 - c. Fostering an adequate supply of well-trained, competent pharmacists and associated personnel.
 - d. Developing and conducting programs for maintaining and improving the competence of pharmacists and associated personnel.
 - e. Disseminating information about pharmaceutical services and rational drug use.
 - f. Improving communication among pharmacists, other members of the health care industry, and the public.
 - g. Promoting research in the health and pharmaceutical sciences and in pharmaceutical services.
 - h. Promoting the economic welfare of pharmacists and associated personnel.
2. To foster rational drug use in society such as through advocating appropriate public policies toward that end.
3. To pursue any other lawful activity that may be authorized by ASHP's Board of Directors.

Fourth. The post office address of the principal office of ASHP in Maryland is 7272 Wisconsin Avenue, Bethesda (Montgomery County), Maryland 20814. The name and post office address of the resident agent of ASHP in Maryland is C.T. Corporation Systems, Inc., 32 South Street, Baltimore, Maryland 21202. The resident agent of ASHP is a Maryland corporation.

Fifth. ASHP shall be a not-for-profit corporation and shall not be authorized to issue capital stock. No part of the net earnings of ASHP, current or accumulated, shall inure to the benefit of any private individual, nor shall ASHP be operated for the primary purpose of carrying on a trade or business for profit. ASHP intends to avail itself of any and all tax benefits or exemptions to which it may be entitled under Section 501 of the Internal Revenue Code of 1954, and it shall not operate or engage in any activity nor shall it possess or exercise any power that would substantially risk the loss of such benefits under that Code.

Sixth. The number of Directors of ASHP shall be 12, which number may be increased or decreased only by amendment to this Charter. The Board of Directors shall consist of six Directors who shall be elected at large by a majority of votes cast by active members; the Chair of the House of Delegates; and the officers of ASHP, to wit, the President, the President-elect, the Immediate Past President, the Treasurer, and the Secretary. The Directors, who shall act until the first annual meeting or until their successors are duly chosen and qualified, as set forth in the Bylaws, are Roger W. Anderson, John A. Gans, Thomas J. Garrison, Clifford E. Hynniman, Marianne F. Ivey, Herman L. Lazarus, Harland E. Lee, Arthur G. Lipman, Joseph A. Oddis, Judith A. Patrick, Paul G. Pierpaoli, and Marilyn L. Slotfeldt. The Directors of ASHP shall manage its business affairs. All Directors shall be active members of ASHP.

Seventh. The following provisions are hereby adopted for the purposes of defining, limiting, and regulating the internal affairs of ASHP:

1. The membership of ASHP shall consist of active members, associate members, honorary members, and such other categories as may be established in the Bylaws. Active members shall be licensed pharmacists who support the purposes of ASHP as stated in the Article Third of this Charter; the other requirements for active membership shall be stated in the Bylaws. Only active members may (a) vote as individual members on amendment to this Charter as provided in Charter item 11, (b) serve as state delegates to the House of Delegates, (c) elect the Directors of ASHP, and (d) serve as a Director of ASHP. The definition, rights, powers, and obligations of each class of members not set forth herein shall be established and limited by the Bylaws.
2. ASHP shall have a House of Delegates that shall meet yearly to review, consider, and ultimately approve or disapprove the professional policies recommended to it by its Directors and to review the affairs of ASHP; voting delegates in the House of Delegates shall consist of the following classes: state delegates, who shall be active members and shall be deemed to represent the aliquot portion of the active membership of ASHP, plus Directors, plus eligible Past Presidents of ASHP, plus fraternal delegates, plus the chair of each Section and Forum created by the Board pursuant to Article 6.1.6 of the bylaws.
 - 2.1. The House of Delegates shall have at least two state delegates from each state.
 - 2.2. The House of Delegates shall elect a Chair to preside at all of its meetings.

3. ASHP may establish and shall try to promote and strengthen ongoing cooperative relationships with other domestic and international organizations when such relationships further the purposes of ASHP.
4. ASHP shall try to formally recognize, promote, and strengthen relationships with groups of pharmacists in the various states and possessions of the United States when such groups promote and foster the purposes of ASHP.

Eighth. Upon termination, dissolution, or winding up of ASHP, any assets that remain after payment or provision for payment of all of its liabilities, debts, and obligations shall be distributed by the Board of Directors only to one or more organized charitable, educational, scientific, or philanthropic organizations duly qualified as exempt under Section 501(c)(3) of the Internal Revenue Code of 1954 (or under such successor provision of the Internal Revenue Code as may be in effect at the time of termination, dissolution, or winding up of ASHP). Under no circumstances shall any assets be distributed to any member of ASHP.

Ninth. The private property of the members, officers, Directors, and employees of ASHP shall not be subject to payment of any debts or obligations of ASHP.

Tenth. The Bylaws shall delineate the authority of the Board of Directors and govern the internal affairs of ASHP. The Bylaws may be amended as provided therein.

Eleventh. Any proposed amendment to this Charter must first be submitted to the Board of Directors. Upon review, the Board shall submit the proposed amendment to the House of Delegates. Upon approval of a majority of the voting delegates of the House of Delegates then present and voting, it shall be submitted to the entire active membership for vote by mail ballot in the same manner as in the election of officers as provided in the Bylaws and shall be sent out as part of the ballot for officers.

Twelfth. The duration of ASHP shall be perpetual.

1 **BYLAWS**

2 **Article 1. Name and Seal**

3 **1.1.** The name of the corporation shall be the “American Society of Health-System
4 Pharmacists, Inc.,” which will be referred to as ASHP.

5 **1.1.1.** The official corporate seal of ASHP, which shall be used as needed to
6 authenticate documents of ASHP, shall consist of the word “Seal” as
7 authorized by Section 1-304 of the Corporations and Associations Article of
8 the Code of Maryland.

9 **1.2.** ASHP may adopt and use such trade names, trademarks, service names, and service
10 marks as, in its judgment, are necessary or appropriate to identify or designate its
11 products and services and to carry on its business.

12 **1.2.1.** No member, chapter, organizational component, or third party may use any
13 name or mark of the ASHP unless such use conforms to the standards
14 established by the Board of Directors and unless the Board has specifically
15 approved such use in writing.

16 **Article 2. Offices and Agent**

17 **2.1.** ASHP shall continuously maintain, in the state of Maryland, a registered office at
18 such place as may be established by the Board of Directors. The Board of Directors
19 may establish ASHP’s principal place of business and other offices and places of
20 business either inside or outside the state.

21 **2.2.** ASHP shall continuously maintain a registered agent within the state of Maryland,
22 which shall be designated, from time to time, by the Board of Directors.

23 **Article 3. Membership**

24 **3.1.** The classifications of membership in ASHP are as follows:

25 **3.1.1.** *Active Members:* Pharmacists licensed by any state, district, or territory of the
26 United States who have paid dues as established by ASHP; practice in the 50
27 jurisdictions of the United States, the District of Columbia, or Puerto Rico;
28 and who support the purposes of ASHP as stated in the Article Third of the
29 ASHP Charter.

30 **3.1.1.1.** Only active members may vote on amendment to the Charter, serve
31 as state delegates, and elect or serve as a Director of ASHP.

32 **3.1.2.** *Associate Members:* Persons who have paid the dues as established by ASHP
33 and who, by virtue of vocation, training, education, and interest, wish to
34 further the purposes of ASHP. Associate members shall consist of the
35 following categories:

36 **3.1.2.1.** *Supporting:* Individuals, other than those who qualify as active
37 members, who by working in the health services, teaching
38 prospective pharmacists, or otherwise contributing to pharmacy
39 services provided in organized health care systems, make themselves
40 eligible for membership.

- 41 **3.1.2.2.** *Student:* Individuals enrolled full time in a pharmacy practice degree
42 program (graduate or undergraduate) in an accredited college of
43 pharmacy.
- 44 **3.1.2.3.** *International:* Pharmacists who are engaged in practice outside the
45 United States of America ~~and its possessions and who are not~~
46 ~~citizens of the United States~~; individuals, other than pharmacists,
47 who are interested in pharmacy as practiced in an organized health
48 care system, and reside outside the United States and its possessions;
49 ~~and are not citizens of the United States.~~
- 50 **3.1.2.4.** *Pharmacy Support Personnel:* Technicians and other individuals
51 who are employed as support personnel in a health care system.
- 52 **3.1.3.** *Honorary Members:* Persons who shall be elected for life by unanimous vote
53 of the Board of Directors from among individuals who are or have been
54 especially interested in, or who have made outstanding contributions to,
55 pharmacy practice in organized health care systems. Honorary members may
56 vote or hold office if otherwise eligible for active membership. No dues shall
57 be required of honorary members.
- 58 **3.2.** The Board of Directors shall establish dues and membership periods for all
59 members.
- 60 **3.2.1.** Persons seeking membership in ASHP shall complete the application form
61 and enclose payment of dues for the classification of membership being
62 sought.
- 63 **3.2.2.** Payment of dues each year automatically renews membership in ASHP;
64 failure to pay timely dues constitutes termination of membership. If dues are
65 paid after membership has terminated, ASHP may treat such payment as a
66 reinstatement of membership.
- 67 **3.2.3.** A member may terminate membership, at any time, by submitting a signed,
68 written statement to ASHP.
- 69 **3.2.4.** Members shall, at the time of application or at renewal, be classified into the
70 category of membership for which they qualify.
- 71 **3.3.** Members of ASHP shall be entitled to receive such services and publications as the
72 Board of Directors establishes.
- 73 **3.3.1.** All active members of ASHP shall receive the *American Journal of Health-*
74 *System Pharmacy* as part of dues. Other classifications or categories of
75 members shall be provided the *American Journal of Health-System Pharmacy*
76 as part of dues as determined by the Board of Directors.
- 77 **3.3.2.** The Board of Directors may establish a service or publication as part of dues
78 or for a separate fee and may establish different services and publications and,
79 for various categories of members, different prices for the same service or
80 publication.
- 81 **3.3.3.** Upon termination of membership, a member's right to membership services
82 shall cease.
- 83 **3.3.4.** Nothing herein shall affect the rights of members to vote or attend the House
84 of Delegates meeting, to the extent those rights are set forth in the Charter or
85 Bylaws.

86 **Article 4. Officers**

87 **4.1.** The officers of ASHP shall be the President, the President-elect, the Immediate Past
88 President, the Treasurer, and the Secretary, all of whom shall be active members of
89 ASHP. The Secretary shall also serve as Executive Vice President of ASHP.

90 **4.1.1.** The President-elect shall be elected annually for a term of one year and shall
91 succeed successively to the office of President and then to the office of
92 Immediate Past President, serving for one year in each office.

93 **4.1.2.** The Executive Vice President shall be chosen by the Board of Directors.

94 **4.1.3.** The candidates for Treasurer shall be nominated by the Board of Directors and
95 elected by the House of Delegates active members for a term of office of three
96 years. No person shall serve more than two successive terms as Treasurer.

97 **4.1.4.** Each officer shall be installed at the yearly meeting of the House of Delegates.

98 **4.1.5.** The President, President-elect, Immediate Past President, and Treasurer are
99 not charged with executive or administrative responsibility for the
100 management or conduct of the internal affairs of ASHP.

101 **4.2.** The President shall serve as the principal elected official of ASHP; serve as Chair of
102 the Board of Directors; serve as Chair of the Committee on Resolutions; at the
103 House of Delegates, communicate to the delegates on the actions of the Board of
104 Directors and on important new activities that affect and further the purposes of
105 ASHP; and communicate with members of ASHP, affiliated chapters, and the public
106 on the activities and policies of ASHP.

107 **4.2.1.** With the approval of the Board of Directors, the President shall annually
108 appoint Chairs and members of the councils, commissions, committees, and
109 other appropriate components set forth in Article 6 of these Bylaws and any
110 ad hoc committee or groups that the Board of Directors establishes.

111 **4.2.2.** The President shall be an ex-officio member of all councils and committees of
112 the Board of Directors and all ad hoc committees.

113 **4.2.3.** The President shall report to the Board of Directors on official activities and
114 shall advise the Board of Directors on such matters as may further the
115 purposes of ASHP.

116 **4.3.** The President-elect shall perform the duties of the President in the President's
117 absence; succeed to that office upon the death, resignation, or inability of the
118 President to perform the duties of that office; serve as Vice Chair of the Board of
119 Directors; and assist in communicating the policies and activities of ASHP to its
120 affiliated chapters, members, and the public.

121 **4.3.1.** The President-elect shall communicate to the House of Delegates and the
122 membership on those issues and activities that may affect and further the
123 purposes of ASHP.

124 **4.3.2.** The President-elect shall report to the Board of Directors on official activities
125 and shall advise the Board of Directors on such matters as may further the
126 purposes of ASHP.

127 **4.3.3.** A President-elect who succeeds to the office of President as provided in
128 Section 4.3 shall serve out both the unfinished term to which he or she has
129 succeeded and the term to which he or she would have succeeded in due
130 course.

- 131 | **4.3.4.** The President-elect shall be nominated ~~under authority~~ by the Committee on
132 | Nominations of the House of Delegates and elected by the active membership
133 | of ASHP as set forth in Article 7 of these Bylaws.
- 134 | **4.4.** The Immediate Past President shall perform the duties of the President in the
135 | temporary absence of both the President and President-elect, serve as Vice Chair of
136 | the House of Delegates, and serve in such other capacity as may be designated by
137 | the Board of Directors.
- 138 | **4.4.1.** The Immediate Past President shall report to the Board of Directors on his or
139 | her activities and shall advise the Board of Directors on such matters as may
140 | further the purposes of ASHP.
- 141 | **4.5.** The Treasurer shall serve as the Chair of the Committee on Finance, as specified in
142 | Section 5.2; be responsible for overseeing conservation and prudent investment of
143 | the assets and funds of ASHP; assure expenditure of funds is in accord with the
144 | programs, priorities, and budget established by the Board of Directors; and regularly
145 | inform the Board of Directors, members, and House of Delegates on the financial
146 | strength and needs of ASHP.
- 147 | **4.5.1.** No monies shall be disbursed except upon signature of the Treasurer and the
148 | Executive Vice President. The Treasurer shall periodically review and
149 | approve internal controls designed to assure proper control of funds and
150 | disbursements and make sure that current and projected income and expenses
151 | meet the budget of ASHP.
- 152 | **4.5.2.** The Board of Directors may, at all times, inspect and verify the books and
153 | accounts of ASHP.
- 154 | **4.5.3.** The Treasurer shall review and report upon the long-term financial projections
155 | and plans of ASHP.
- 156 | **4.6.** The Executive Vice President shall serve as the chief executive officer and as
157 | Secretary of ASHP.
- 158 | **4.6.1.** The Executive Vice President shall be responsible for administration of
159 | ASHP; direction of all operations, programs, and activities of ASHP; and
160 | hiring, firing, and the compensation and benefits of staff, subject to
161 | establishment of general salary and benefit policies by the Board of Directors.
162 | The Executive Vice President shall, at all times, carry out the policy aims and
163 | programs as generally determined by the Board of Directors.
- 164 | **4.6.2.** As Secretary, the Executive Vice President shall keep and maintain an
165 | accurate record of the meetings of the Board of Directors, the House of
166 | Delegates, and such other activities of ASHP as the Board of Directors may
167 | direct. The Executive Vice President shall give all notices required by law.
168 | The Executive Vice President shall have authority to affix the corporate seal
169 | to any document requiring it and attest thereto by his or her signature.
- 170 | **4.6.3.** The Executive Vice President may appoint an Assistant Secretary to attest to
171 | documents.
- 172 | **4.6.4.** The Executive Vice President shall, by virtue of the office, be a nonvoting
173 | member of all councils, commissions, and committees of the Board of
174 | Directors; committees of the House of Delegates; and any other committee or
175 | component group established by the Board of Directors.

- 176 **4.6.5.** The Executive Vice President shall be chosen by and serve at the pleasure of
177 the Board of Directors. The Board of Directors may, on behalf of ASHP, enter
178 into a contract with the Executive Vice President with such terms and for such
179 fixed period as the Board of Directors deems reasonable and in the best
180 interests of ASHP. Failure of a person to continue in the office of Executive
181 Vice President will not affect contract rights, except as the terms of that
182 contract may so provide.
- 183 **4.7.** The manner of filling vacancies of any office shall be as follows:
- 184 **4.7.1.** The provision of Sections 4.3 and 4.3.3 shall apply.
- 185 **4.7.2.** If both the President and the President-elect shall become permanently unable
186 to perform the duties of their offices, the Board of Directors shall appoint,
187 from the Board of Directors, a President Pro Tempore to serve for the
188 remaining portion of the unexpired term. At the next yearly meeting of the
189 House of Delegates, the Committee on Nominations shall present nominations
190 for the offices of President and President-elect, and an election shall be
191 conducted in accordance with the provisions of Article 7 of these Bylaws.
- 192 **4.7.3.** If the Executive Vice President or the Treasurer becomes unable to perform
193 the duties of his or her office, the Board of Directors is empowered to fill that
194 vacancy.
- 195 **4.7.4.** If the Immediate Past President is permanently unable to perform the duties of
196 that office, the Board of Directors shall appoint a Director of ASHP to
197 perform the duties of that office.
- 198 **4.8.** The following miscellaneous provisions shall apply:
- 199 **4.8.1.** To the extent not prohibited by these Bylaws, the officers may also exercise
200 the powers that, by statute or otherwise, are customarily exercised by officers
201 holding such offices or that may be established by the Board of Directors.
202 However, only the Executive Vice President or an individual appointed by the
203 Executive Vice President may execute, on behalf of ASHP, contracts, leases,
204 debt obligations, and all other forms of agreement. An officer of ASHP may
205 sign an instrument that must be executed by the Executive Vice President and
206 that other officer. The Board of Directors may authorize any two officers to
207 jointly execute a specific document or instrument.
- 208 **4.8.2.** Except to the extent specifically authorized by the Board of Directors, no
209 officer shall be entitled to any compensation for services. In accordance with
210 policies established by the Board of Directors, officers may be reimbursed for
211 reasonable expenses incurred in discharging the functions of the office.

212 **Article 5. Board of Directors**

- 213 **5.1.** The Board of Directors shall consist of 12 persons: the officers of ASHP, the Chair
214 of the House of Delegates, and six Directors at large.
- 215 **5.1.1.** The term of office for a Director, who also serves as an officer or as Chair of
216 the House of Delegates, shall be the term for that office, and the manner of
217 election and filling vacancies in such offices shall be as specified in the
218 Bylaws dealing with those offices.
- 219 **5.1.2.** Directors at large shall be nominated ~~under the auspices~~ by the Committee on
220 Nominations of the House of Delegates and elected as set forth in Section 7.4.

- 221 | **5.1.3.** Elected Directors shall serve for ~~one~~ term of three years beginning with
222 | installation at the yearly meeting of the House of Delegates following their
223 | election. Elected Directors may not serve more than ~~two consecutive terms~~
224 | one term as a member at large.
- 225 | **5.1.4.** If the office of an elected member of the Board of Directors shall become
226 | vacant between yearly meetings of ASHP because of resignation, death, or
227 | otherwise, the Board of Directors may fill the vacancy. At the next yearly
228 | meeting of the House of Delegates, the Committee on Nominations shall
229 | present candidates for election to serve for the remaining portion of the
230 | unexpired term.
- 231 | **5.2.** The Committee on Finance shall report to the Board and shall consist of the
232 | President, the President-elect, the Immediate Past President, the Executive Vice
233 | President, and the Treasurer; the Treasurer shall be its Chair. The Committee on
234 | Finance shall prepare a budget for the forthcoming year and submit it to the Board
235 | of Directors for approval; review, assess, and monitor operations of ASHP to assure
236 | that budget objectives are met or that appropriate changes thereto are made; review
237 | and assess performance of investments and assets of ASHP; review all investment
238 | policies and financial policies of ASHP; oversee the responsibilities of the Treasurer
239 | set forth in Section 4.5; and oversee the financial operations of ASHP.
- 240 | **5.3.** The Board of Directors shall meet annually, in conjunction with the yearly meeting
241 | of the House of Delegates, and at such other times as the Board may determine. A
242 | special meeting shall be held upon written application of any three Directors or of
243 | the President.
- 244 | **5.3.1.** The Secretary shall establish the time and place of scheduled and special
245 | meetings and shall give the Directors reasonable advance notice thereof by
246 | mail or other mode of transmittal.
- 247 | **5.3.2.** No Director shall be entitled to any compensation for services. Pursuant to
248 | policies adopted by the Board, Directors may be reimbursed for reasonable
249 | expenses incurred in attending meetings of the Board of Directors and in
250 | discharging functions at the direction of the Board.
- 251 | **5.4.** The Board of Directors shall manage the affairs of ASHP, establish policies within
252 | the limits of the Bylaws, actively pursue the purposes of ASHP, and have discretion
253 | in the control, management, investment, and disbursement of its funds. The Board of
254 | Directors, through its Committee on Finance, shall develop and approve an annual
255 | budget, establish financial goals for ASHP, and oversee the financial operations of
256 | ASHP. The Board of Directors shall establish and review long-term objectives of
257 | ASHP and establish the priority of all programs and activities. The Board may
258 | establish whatever rules and regulations for the conduct of its business it deems
259 | advisable and may appoint whatever agents it considers necessary to carry out its
260 | powers.
- 261 | **5.4.1.** The Board of Directors may establish committees and task forces and
262 | designate representatives to other organizations.
- 263 | **5.4.2.** The Board of Directors may make contributions of ASHP assets to other
264 | organizations for research and education activities of benefit to pharmacists
265 | practicing in organized health care systems. The Board may also accept

- 266 grants, contributions, gifts, bequests, or devices to further the purposes of
267 ASHP.
- 268 **5.4.3.** The Board of Directors shall create, review, and modify the professional
269 policies of ASHP and submit those policies to the House of Delegates for such
270 action as the House of Delegates may choose to take under Article 7. The
271 Board of Directors shall approve or disapprove all recommendations of the
272 components of ASHP set forth in Article 6 and any committee or group
273 created by, or which reports to, the Board of Directors. Further, the Board of
274 Directors shall report annually to the House of Delegates how it has handled
275 such recommendations so that the House of Delegates can take final action as
276 required or appropriate under Article 7.
- 277 **5.4.4.** The Board of Directors shall approve all nominations to all committees,
278 councils, and commissions, except as membership is specified in Article 6.
- 279 **5.4.5.** The Board of Directors may establish and modify administrative policies, not
280 inconsistent with these Bylaws, for the conduct of its business and for the
281 conduct of the business of ASHP and its components, except for the House of
282 Delegates, which may establish its own regulations.
- 283 **5.4.6.** The Board of Directors and the officers shall tender reports at such times and
284 in such manner as are required by law.

285 **Article 6. Components**

- 286 **6.1.** The Board of Directors may establish councils, commissions, committees, joint
287 committees, sections, forums and other appropriate component groups of ASHP, and
288 such components shall operate to further the purposes of ASHP. The Board of
289 Directors may modify, change, or eliminate components based on the needs of
290 ASHP and its membership.
- 291 **6.1.1.** The Commission on Credentialing shall consist of a Chair and as many ASHP
292 members and individuals from other disciplines as may be deemed necessary.
293 The Commission shall formulate and recommend standards for accreditation
294 of pharmacy personnel training programs, administer programs for
295 accreditation of pharmacy personnel training programs, and perform such
296 other functions as related to the development and recognition of pharmacy
297 personnel and areas of pharmacy practice as may be assigned by the Board of
298 Directors.
- 299 **6.1.1.1.** One or more members shall be appointed from the public sector.
300 **6.1.1.2.** The term of appointment shall not exceed three years. Commission
301 members may be appointed to subsequent terms.
- 302 **6.1.2.** ASHP shall have councils that report to the Board of Directors and
303 recommend professional policy positions within their areas of concern.
304 Councils may also review ongoing activities of ASHP and recommend new
305 programs within their areas of interest. The councils shall consist of a Chair
306 and those members appointed by the President, with the approval of the Board
307 of Directors. The President shall appoint a Director to each council who shall
308 attend all meetings of the council as an observer and present council
309 recommendations to the Board of Directors.

310 **6.1.3.** The President, with the approval of the Board of Directors, may establish and
311 appoint joint committees with other organizations. Joint committees shall
312 meet to discuss and recommend to each parent organization solutions to
313 problems of mutual interest.

314 **6.1.4.** Sections and Forums are components of ASHP established by the Board of
315 Directors. The Board of Directors may also establish rules and criteria
316 (including financial criteria) to join and maintain enrollment in a Section or
317 Forum for the administration of the affairs of the Section or Forum. ASHP
318 members who meet the criteria may be members of the Section or Forum.

319 **6.1.4.1.** Sections and Forums shall be operated to further the purposes of
320 ASHP by fostering the development, enhancement, and
321 recognition of pharmacy practice as represented by the Section or
322 Forum.

323 **6.2.** The components of ASHP established pursuant to this Article 6 shall have only
324 those powers granted herein. The Board of Directors may establish administrative
325 guidelines for the scope and operation of these components.

326 **6.2.1.** In no case shall a component independently contact other organizations, seek
327 or attempt to secure funds from outside ASHP, or commit any funds of ASHP
328 without prior authorization from the ASHP Board of Directors.

329 **Article 7. House of Delegates**

330 **7.1.** The House of Delegates shall consist of 163 voting state delegates, who shall
331 represent a proportionate number of active members in each state; plus all Directors
332 of ASHP; plus Past Presidents (if active members) after completing the term of
333 office of Immediate Past President; plus five (voting) fraternal delegates; plus the
334 (voting) chair of each Section and Forum. Each delegate shall have one vote, and no
335 delegate may have more than one vote by virtue of any dual capacity in the House of
336 Delegates.

337 **7.1.1.** Delegates shall be chosen as follows:

338 **7.1.1.1.** As soon as convenient after July 1 in every fourth year beginning
339 with the year 1983, the Board of Directors shall apportion 163
340 delegates among the states in proportion, as nearly as can be, to the
341 total of active ASHP members in each state as recorded. Each state
342 shall have at least two delegates. For the purpose of computing the
343 reapportionment, the Board of Directors shall use the total number
344 of active members during the immediately preceding year. This
345 apportionment shall prevail until the next quadrennial
346 apportionment, whether the ASHP membership from a particular
347 state increases or decreases.

348 **7.1.1.2.** Affiliated state chapters shall administer the election of voting
349 state delegates for the House of Delegates. The chapter shall
350 conduct an election to elect voting state delegates from among the
351 active members of ASHP within that state; only active members
352 shall vote in that election. Each state shall certify and transmit, to
353 the Executive Vice President of ASHP, the names and addresses of
354 the elected delegates, and such delegates shall be deemed

- 355 thereupon to be duly qualified. Delegates shall continue in office
356 until the next election and certification. Any issue or question
357 relating to qualification or eligibility of any delegate or alternate
358 shall be referred to and resolved by the ASHP Board of Directors.
- 359 **7.1.1.3.** In those states where no affiliated state chapter exists, the President
360 of ASHP shall appoint, from among the active members of ASHP
361 in the state, a committee of three, designating a Chair and a
362 Secretary, for the purpose of conducting an election for delegates
363 and alternates from active members in the state.
- 364 **7.1.1.4.** The United States Army, Navy, Air Force, Public Health Service,
365 and Veterans Administration shall each be entitled to designate one
366 voting fraternal delegate.
- 367 **7.1.1.5.** Alternates for voting state delegates shall be chosen in the same
368 manner as that designated for choosing voting state delegates.
369 Alternates shall not be entitled to any of the rights or privileges for
370 delegates until, pursuant to the Rules of Procedure of the House of
371 Delegates, the alternate replaces a voting state delegate.
- 372 **7.1.2.** The House of Delegates shall elect a Chair who shall be installed immediately
373 upon election and serve ~~until expiration of the term of office at the next yearly~~
374 ~~session of the House of Delegates~~ a three-year term.
- 375 **7.1.2.1.** The Chair shall be elected by written or electronic ballot of a
376 majority vote of the delegates present and voting in the House of
377 Delegates. The Chair may ~~succeed to that office but may not~~ serve
378 for more than one three ~~successive terms.~~ year term.
- 379 **7.1.2.2.** The Chair shall serve as liaison between the submitter of reso-
380 lutions for consideration by the House of Delegates and the
381 Committee on Resolutions.
- 382 **7.1.3.** The Immediate Past President shall serve as Vice Chair of the House of
383 Delegates.
- 384 **7.1.4.** The Executive Vice President of ASHP shall serve as Secretary of the House
385 of Delegates.
- 386 **7.1.5.** Members of ASHP shall have no right to vote in the House of Delegates
387 except by virtue of status hereunder.
- 388 **7.2.** A yearly session (consisting of at least two meetings) of the ASHP House of
389 Delegates shall be held at such time and place as may be established; the House of
390 Delegates shall conduct such business as may come before it. Special online
391 sessions of the House of Delegates may be called by the Board of Directors or by the
392 Chair of the House of Delegates ~~upon written request of 108 voting state delegates,~~
393 provided that such request contains the specific topic or topics to be considered at
394 that meeting.
- 395 **7.2.1.** The Secretary shall notify each member selected as a delegate to the House of
396 Delegates at least 30 days in advance of its yearly session and any special
397 session.
- 398 **7.2.2.** ASHP shall use reasonable means to notify the membership of yearly and
399 special sessions and to encourage their participation therein, to the extent
400 authorized by these Bylaws.

401 **7.2.3.** A majority of voting members of the House of Delegates who have enrolled
402 for that session shall constitute a quorum at any session or meeting duly
403 convened. In the absence of a quorum, the Chair may recess any session or
404 meeting until such time as a quorum is present.

405 | **7.3.** The House of Delegates shall conduct its business at its yearly or special online
406 session.

407 **7.3.1.** The House of Delegates shall review and oversee the professional affairs of
408 ASHP to further its purposes.

409 **7.3.1.1.** ASHP professional policy, as approved by the Board of Directors,
410 shall be submitted to the House of Delegates for its review,
411 consideration, modification, approval, or disapproval. In the event
412 the House of Delegates fails to approve a matter as submitted to it,
413 the House shall note the reason in its proceedings and return the
414 matter to the Board of Directors for review, modification, or other
415 action. The Board of Directors shall consider, during its interim
416 meeting between meetings of a House of Delegates session, actions
417 of the House of Delegates that resulted in amendment or
418 modification of an issue presented in the first House meeting. The
419 Board shall report its recommendations pertaining to these
420 amendments or modifications during its report in the second
421 meeting of the House session. If, after Board reconsideration, the
422 House disagrees with the Board recommendation pertaining to
423 disposal of an issue, the House may, by two-thirds vote of certified
424 and registered delegates, reconsider the issue for approval. If, on
425 reconsideration, the House fails to approve the matter as previously
426 amended or modified, the House shall note the reason in its
427 proceedings and return the matter to the Board of Directors for
428 review, modification, or other action. The Board of Directors shall
429 then duly report its action thereon at the next session of the House
430 of Delegates.

431 **7.3.1.2.** Individual delegates may make recommendations to the Board of
432 Directors on such matters as each delegate deems appropriate.

433 **7.3.1.3.** As to any resolution or item of business presented to the House,
434 the Board shall normally certify that it has duly considered the
435 matter. However, if the House of Delegates should debate a matter
436 that the Board of Directors has not so considered, action taken by
437 the House will be by vote to refer the proposed matter to the Board
438 of Directors for review before the House of Delegates takes action
439 on that matter or to reject the issue. The Board shall report on that
440 matter for consideration by the House at the next session of the
441 House of Delegates. If the Board of Directors rules that bona fide,
442 extraordinary circumstances require immediate action and if a
443 majority of the delegates present and voting concur, the House of
444 Delegates may exercise extraordinary authority and amend,
445 modify, or substitute any matter placed before it.

- 446 **7.3.2.** By majority vote, the House of Delegates may establish its Rules of
447 Procedure, to be effective at the next meeting of the House.
- 448 **7.3.3.** All officers and Directors of ASHP shall be installed before the House of
449 Delegates at the commencement of their individual terms of office.
- 450 **7.3.4.** The House of Delegates shall, except as is otherwise specifically provided for
451 in these Bylaws, have no authority over the financial affairs of ASHP.
- 452 **7.3.5.** The Chair of the House of Delegates shall preside at all sessions and meetings
453 of the House of Delegates, shall be a member of the Board of Directors, and
454 shall represent the House of Delegates at all Board meetings.
- 455 **7.4.** Election of Directors of ASHP shall be conducted by, or under the auspices of, the
456 Committee on Nominations of the House of Delegates.
- 457 **7.4.1.** The Treasurer shall be elected by written or electronic ballot of a majority
458 vote of the ~~delegates present and voting in the House of Delegates active~~
459 membership in the same manner as members at large as provided in Section
460 7.4.3.2. every third year before the term of that office begins. Only
461 nominations for the office of Treasurer from the Board of Directors shall be
462 accepted.
- 463 **7.4.2.** The Chair of the House of Delegates shall be elected by written or electronic
464 ballot of the House of Delegates as provided in Section 7.1.2.
- 465 **7.4.3.** The Chair shall appoint a Committee on Nominations consisting of seven
466 active members ~~who shall be delegates to the House of Delegates at the time~~
467 ~~of their appointment to serve as a Committee of the House.~~ The Committee
468 shall solicit names of possible candidates for office using such means as it
469 determines to be appropriate.
- 470 **7.4.3.1.** The Committee shall submit to the House of Delegates one or
471 more reports nominating two candidates for the office of President-
472 elect, two candidates for each Director to be elected, and two
473 candidates each for Chair of the House of Delegates. The reports
474 of the Committee shall not be subject to amendment and shall be
475 the exclusive source of nominations for these offices.
- 476 **7.4.3.2.** The names of the candidates for President-elect, Treasurer, and
477 Directors of ASHP shall be submitted by mail or electronic
478 transmission to every active member of ASHP within 60 days after
479 nomination. The active member shall indicate on the ballot a
480 choice of candidates for the offices to be filled and return the same
481 by mail or electronic transmission within 30 days of the date on the
482 ballot.
- 483 **7.4.3.3.** The ballots, postmarked or electronically transmitted within 30
484 days of the date printed on the ballot, will be submitted to the
485 Board of Canvassers who shall oversee counting of the ballots. The
486 Board of Canvassers shall certify the results of the election to the
487 Executive Vice President. The Executive Vice President shall
488 notify all candidates of the results of the election, and the results of
489 the election shall also be disseminated to the membership.
- 490 **7.4.3.4.** The Board of Directors shall fill all vacancies in the list of
491 candidates that may occur by death or resignation after the

492 adjournment of the annual meeting of ASHP and before the
493 issuance of mail ballots.

494 **7.5.** The Committee on Resolutions shall be composed of the Board of Directors and
495 chaired by the President of the Society. The Committee shall review all resolutions.
496 Once duly considered, the Committee shall submit them to the House of Delegates.

497 **Article 8. Affiliated State Chapters**

498 **8.1.** ASHP shall recognize groups of pharmacists practicing in organized health care
499 systems within the states when such groups promote the purposes of ASHP.

500 **8.1.1.** Only one group in each state (hereafter, affiliated state chapter) shall be
501 affiliated with ASHP.

502 **8.1.2.** ASHP shall establish standards and criteria that a state group must meet to be
503 affiliated with ASHP.

504 **8.2.** ASHP shall promote and strengthen affiliations with affiliated state chapters in order
505 to support and fulfill the mission of ASHP and its affiliates.

506 **8.2.1.** Affiliated state chapters shall promote the standards and policies of ASHP
507 within the state.

508 **8.2.2.** Affiliated state chapters may use the official Society logo and note its
509 affiliation with ASHP under such terms and conditions as may be established
510 by the Board of Directors.

511 **8.2.3.** Within the limits of its resources, ASHP shall endeavor to provide services,
512 benefits, and programs to assist affiliated state chapters in furthering the
513 purposes of ASHP and in furthering the organizational strength of affiliated
514 state chapters.

515 **8.2.4.** Affiliated state chapters shall administer the election of voting state delegates
516 to the House of Delegates.

517 **8.2.5.** Affiliated state chapter involvement is critical to ASHP and should advance
518 the best interests of the membership at the national and state levels, encourage
519 and facilitate two-way information exchange and support between ASHP and
520 the affiliate, and provide benefits to ASHP and the affiliate.

521 **8.3.** Affiliation shall not limit the rights of ASHP or the affiliated state chapter.

522 **8.3.1.** Affiliated state chapters may not adopt, publicize, promote, or otherwise
523 convey any policy or principle in the name of the American Society of Health-
524 System Pharmacists that has not been officially adopted by ASHP.

525 **8.3.2.** Acts of affiliated state chapters shall in no way commit or bind ASHP.

526 **8.3.3.** Dues in affiliated state chapters may be set at the discretion of the chapter.
527 Dues in ASHP shall be established pursuant to these Bylaws.

528 **Article 9. International Cooperation**

529 **9.1.** ASHP shall endeavor to promote and foster relationships with pharmacy
530 organizations from other countries and with international pharmacy and health
531 organizations when such furthers the purposes of ASHP.

532 **Article 10. Miscellaneous**

533 **10.1.** The following terms used in these Bylaws shall mean the following:

- 534 | **10.1.1.** “Notice” shall be ~~either~~ delivered personally, electronically, or ~~mailed~~
535 | ~~(including the sending of a telegram)~~ by mail to the business primary address
536 | of the person to receive such notice. If such notice is given by mail, it shall
537 | be deemed delivered when deposited in the United States mail properly
538 | addressed and with postage paid thereon. ~~If such notice is given by~~
539 | ~~telegram, it shall be deemed delivered when the content of the telegram is~~
540 | ~~delivered to the telegraph company.~~
- 541 | **10.1.2.** “State” shall mean the 50 jurisdictions of the United States customarily
542 | called states, plus the District of Columbia and Puerto Rico.
- 543 | **10.2.** At the direction of the Board of Directors, any officer or employee of ASHP shall
544 | furnish, at the expense of ASHP, a fidelity bond in such a sum as the Board shall
545 | provide.
- 546 | **10.3.** ASHP may indemnify each Director, officer, former Director, and former officer of
547 | ASHP against expenses (including attorneys’ fees), judgments, fines, penalties, and
548 | settlements actually and necessarily incurred by that person in connection with or
549 | arising out of any proceeding in which that person may be involved as a party or
550 | otherwise by reason of being or having been such Director or officer.
- 551 | **10.3.1.** No indemnification shall be made until the Board of Directors or ASHP
552 | shall have determined that indemnification is proper.
- 553 | **10.3.2.** The procedure and standard for indemnification shall be governed by the
554 | applicable sections of the Corporations and Associations Article and the
555 | Annotated Code of Maryland.
- 556 | **10.4.** If any provision of these Bylaws should, for any reason, be held to be invalid, the
557 | validity of any other provision is not thereby affected.
- 558 | **10.5.** Whenever the Board of Directors is given authority with respect to any matter, that
559 | authority shall include the ability to modify, change, stop, or eliminate that matter at
560 | any time.
- 561 | **10.6.** The business of the House of Delegates shall be conducted in accord with such
562 | Rules of Procedure as the House of Delegates may establish and, to the extent not
563 | covered therein, by the latest edition of Robert’s Rules of Order. In no case shall
564 | any rule of the House conflict with the Charter or these Bylaws.
- 565 | **10.7.** The fiscal year of ASHP shall be a 12-month period beginning on June 1 and
566 | ending on May 31.
- 567 | **10.8.** The *American Journal of Health-System Pharmacy* shall be the official publication
568 | of ASHP. The proceedings of the House of Delegates and the Board of Directors
569 | and other official business of ASHP shall be published in the *American Journal of*
570 | *Health-System Pharmacy*.
- 571 | **10.9.** ASHP will support a research and education foundation to further development of
572 | the profession and as a means to meet the purposes of ASHP; the research and
573 | education foundation will, at all times, be a separate and independent entity.

574 | **Article 11. Amendment**

- 575 | **11.1.** Any proposed amendment to these Bylaws must first be submitted to the Board of
576 | Directors. Upon review, the Board shall submit the proposed amendment to the
577 | House of Delegates. Upon approval of a majority of the voting delegates of the
578 | House of Delegates then present and voting, the amendment shall become effective.

The ASHP Charter and Bylaws were approved by the ASHP House of Delegates on June 6, 1984, and by active members of the Society in the 1984 mail ballot annual election. These documents, as subsequently amended, replace the Society's former Articles of Incorporation, Constitution, and Bylaws, effective January 1, 1985. The Regulations for the ASHP House of Delegates were not a part of the 1982–84 governing documents modernization project.

Revised ~~07/01/05~~17/14

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ASHP Rules of Procedure for the House of Delegates

579 **Article 1. Summary and Authority**

580 1.1. *Summary*: These Rules of Procedure establish basic rules under which the ASHP
581 House of Delegates operates and conducts its business. These Rules of Procedure
582 are subject to the ASHP Charter and Bylaws but supersede any contrary or
583 inconsistent rule in *Robert's Rules of Order*.

584 1.2. *Authority*: ASHP Bylaws, Section 7.3.2.

585 **Article 2. Rules of Order**

586 2.1. The latest edition of *Robert's Rules of Order* shall govern proceedings of the House
587 of Delegates when not inconsistent or in conflict with these ASHP rules; in such
588 cases, these ASHP rules will govern.

589 2.1.1. In order of precedence, the ASHP Charter and then the ASHP Bylaws, at all
590 times, supersede these ASHP rules and *Robert's Rules of Order*.

591 2.1.2. The House should be guided by formal interpretation of the governing
592 documents as announced by its Chair and by precedent.

593 **Article 3. Seating of Delegates**

594 3.1. Delegates and alternates duly certified and qualified under Section 7.1 of the Bylaws
595 shall be enrolled by the Secretary in advance of a yearly or special session. After
596 the first meeting of a yearly or special session has been called to order, the Secretary
597 shall call the roll of enrolled delegates; those answering the roll shall be recognized
598 as delegates.

599 3.1.1. Any delegate who, at the first meeting of a House of Delegates session, is
600 recognized and enrolled as a delegate of the House shall remain a delegate of
601 the House until such time as replaced pursuant to this rule.

602 3.1.2. The place of a recognized and enrolled delegate will not be taken by any other
603 person, except that at the commencement of each meeting the House may, by
604 majority vote, recognize and enroll an alternate delegate (in order of
605 precedence, if designated by the state) if presented, who shall then remain a
606 delegate (in place of the replaced delegate).

607 3.1.3. In the event neither a delegate nor alternate from a state appears at the
608 commencement of a session of the House, the Secretary shall enroll and the
609 Chair shall recognize the first certified delegate or alternate appearing before
610 the House as the enrolled and recognized delegate from such state.

611 **Article 4. Meetings**

612 4.1. All meetings of the House of Delegates shall be open unless the House of Delegates,
613 by a vote of two-thirds of the total House, as defined in Section 7.1 of the Bylaws,
614 votes to go into executive session. When in executive session, the following only
615 shall be admitted to the room in which the meeting is held: members of the House

616 of Delegates (as defined in Section 7.1 of the Bylaws), the parliamentarian, and
617 others specifically authorized by a majority vote of the House of Delegates.

618 **Article 5. Open Hearing**

619 | 5.1. An open hearing shall be conducted, in conjunction with any in-person House of
620 Delegates session, to provide a forum for members to express their opinions on
621 matter of concern to them and on matters to be considered by the House of
622 Delegates.

623 5.1.1. At the call of the Chair of the House of Delegates, and with approval of the
624 Board of Directors, additional open hearings may be scheduled.

625 5.1.2. The Chair of the House of Delegates shall preside at any open hearing and
626 may request assistance from members of the Board of Directors, officers of
627 the Society, and council Chairs.

628 **Article 6. Privilege of the Floor**

629 6.1. The privilege of the floor (which may include the right to participate in debate on a
630 matter), during a meeting of the House of Delegates, may be extended by either the
631 Chair or the House of Delegates.

632 **Article 7. Conduct of Business of the House**

633 7.1. The ~~Order of Business~~ of the House of Delegates shall be as follows, unless the
634 Chair of the House of Delegates determines that the business or matters for the
635 House require a different order or that additional items to the order are required:

636 a. Call to order.

637 b. ~~Invocation.~~

638 ~~e.~~ Roll call of delegates.

639 ~~d.~~ Reports of officers and the Board of Directors.

640 ~~e.~~ Recommendations of delegates.

641 ~~f.~~ Reports of councils and committees.

642 f. **Resolutions.**

643 g. Unfinished business.

644 h. New business.

645 i. Triennial Election of the ~~Treasurer of the Society.~~

646 ~~i.~~ **Election of** Chair of the House of Delegates.

647 ~~kj.~~ Installation of officers and Directors.

648 ~~lk.~~ Adjournment.

649 7.2. Any matter upon which action is to be taken by the House of Delegates will be
650 presented to delegates in writing and in advance. The Secretary will distribute
651 copies of the proposed action to the House. Action of the House is, at all times,
652 subject to Section 7.3 and, in particular, Section 7.3.1.3 of the Bylaws.

653 7.2.1. Any matter to be presented as new business shall be presented to the Chair of
654 the House in writing no later than four o'clock in the evening before the day
655 of the meeting in which new business is on the agenda. If any such matter
656 will include the offering of a motion, the writing required by this rule shall
657 state explicitly the motion to be offered.

- 658 7.2.2. Resolutions to be considered by the House of Delegates must be presented in
659 writing to the Secretary of the House of Delegates at least 90 days in advance
660 of the session and be signed by at least two active members of ASHP.
661 7.2.2.1. Resolutions not voluntarily withdrawn by the submitter that meet the
662 requirements of the governing documents shall be presented to the
663 House of Delegates by the Committee on Resolutions at the first
664 meeting and acted upon at the second meeting. They shall be
665 submitted to delegates with one of the following recommendations:
666 (a) recommend adoption, (b) do not recommend adoption, (c)
667 recommend referral for further study, or (d) presented with no
668 recommendation of the Committee on Resolutions.
669 Action by the House of Delegates shall be on the substance of the
670 resolutions and not on the recommendation of the Committee on
671 Resolutions.
672 7.2.2.2. The House shall be informed of resolutions not presented to it and the
673 reasons therefore.
674 7.3. Any item presented for action by the House of Delegates shall, unless the Bylaws or
675 these rules specify to the contrary, require for passage the vote required by *Robert's*
676 *Rules of Order*. Except for election of the Chair ~~and Treasurer~~, no vote shall be by
677 secret ballot.
678 7.3.1. Any matter not acted upon by the House of Delegates, upon adjournment of
679 the session, shall die.
680 7.4. Matters of an emergent nature must be acted upon in accord with Section 7.3.1.3. of
681 the Bylaws.

682 **Article 8. Nominations and Elections**

- 683 8.1. Nominations of Directors of ASHP (including the Chair of the House of Delegates)
684 shall be by the Committee on Nominations in accordance with Section 7.4 of the
685 Bylaws.
686 8.1.1. A written biography on each nominee shall be prepared and distributed at the
687 appropriate meeting of the House of Delegates session.
688 8.1.2. The Chair shall appoint three delegates to serve as election tellers for elections
689 conducted in the House of Delegates. Tellers shall supervise the election,
690 count ballots, and report to the Chair the results thereof. The Chair shall share
691 the election results with each nominee but shall announce only the name of
692 the candidate receiving the majority of votes cast for Chair of the House of
693 Delegates.
694 8.1.3. The Chair shall be elected by written or electronic secret ballot of the House
695 of Delegates and need receive only a majority of votes cast.
696 8.1.4. The Committee on Nominations shall issue a separate report containing two
697 nominees for each Director and the office of President-elect.
698 ~~8.1.5. The election of the Treasurer (upon nomination by the Board of Directors)~~
699 ~~shall be in accordance with Section 7.4.1. of the Bylaws.~~

700 **Article 9. Amendments**

701 9.1. Every proposed amendment to the Rules of Procedure for the House of Delegates
702 shall be submitted in writing at one meeting of the House of Delegates and may be
703 acted upon at a subsequent meeting of the session, when upon receiving a majority
704 of votes cast, it shall become a part of these rules, effective as of the following
705 session of the House of Delegates.

Developed by the ASHP Council on Organizational Affairs. Approved by the ASHP Board of Directors, November 20–21, 1985, and by the ASHP House of Delegates, June 4, 1986. Supersedes the previous document, Regulations for the ASHP House of Delegates.

| Revised: ~~9/06/~~ /14/95.

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2014 Report of the ASHP Treasurer

A growing and forward-looking organization

PHILIP J. SCHNEIDER

Am J Health-Syst Pharm. 2014; 71:1418-20

Each year, the ASHP Treasurer has the distinct pleasure of reporting to the membership the financial condition of the Society. The Society's fiscal year is from June 1 through May 31, coinciding with our policy development process and timetable. This report will describe ASHP's financial performance and planning for three periods, providing (1) the final audited prior-year numbers (for fiscal year 2013), (2) current-year (fiscal year 2014) projected performance, and (3) the budget for the fiscal year ending May 31, 2015.

ASHP segregates its finances into two budgets, core and program development. The core budget represents the revenue and expense associated with the core operations of the organization. The program development budget is intended for expenditures that are (1) associated with new, enhanced, or expanded programs; (2) associated with time-limited programs; (3) capital asset purchases; or (4) supplemental operating expenses. The program development budget is funded only from investment income.

The audit of the May 31, 2013, financial statements of the Society

and the Society's subsidiary, the 7272 Wisconsin Building Corp., performed by the firm of Tate & Tryon, resulted in an unqualified opinion. Copies of the audited statements are available by contacting the ASHP Executive Office.

Fiscal Year Ending May 31, 2013—Actual

Last year I reported to you that we were projecting a surplus from both core operations and in the program development budget. That projection proved true, as the Society's increase in net assets before a pension adjustment totaled \$7.1 million (Figure 1). A \$1.8 million pension adjustment pushed the Society's 2013 net increase in net assets to \$8.9 million. The Society's net assets totaled \$34.2 million at May 31, 2013, 70% of total expense. Our long-term financial policy is to maintain net assets at 50% of total ASHP and 7272 Wisconsin Building Corp. expenses, with a floor of at least 35%.

The Society's May 31, 2013, year-end balance sheet (Figure 2) remained impressive, strengthened even more from the 2013 results from operations. The May 31, 2013, asset-

to-liability ratio stood at 2.55:1.00, up from 2.10:1.00 a year ago.

Fiscal Year Ending May 31, 2014—Projected

As of February 28, 2014, financial performance in the core budget for the year ending May 31, 2014, is projected to produce a net income of \$1.7 million (Figure 1). A strong performance in the stock market is expected again in fiscal year 2014 helping to produce a program development budget surplus of \$941,000. Adding the core net income, the program development budget surplus and allowing for \$100,000 net asset spending approved by the Board, the Society's total increase in net assets is projected at \$2.6 million. If we achieve the year-end projections indicated in Figure 1, the Society's net assets at May 31, 2014, will be \$36.8 million, or 74% of the total ASHP and 7272 Wisconsin Building Corp. expense.

Fiscal Year Ending May 31, 2015—Budgeted

The Society's 2015 core budget is essentially a balanced budget (Figure 1), with the core and development budgets combined producing

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a \$243,000 surplus before spending from net assets. Although spending from net assets (\$400,000) will cause an overall deficit for 2015, the Society's total net assets are still projected to be at a strong 65% of total expense.

7272 Wisconsin Building Corp.

The Society's subsidiary, the 7272 Wisconsin Building Corp., finished

the 2013 fiscal year on a positive note, producing net income of \$1.8 million before owner's distribution (Figure 3). The subsidiary owns the headquarters building and derives income from leased commercial and office space.

Conclusion

As your Treasurer, I am pleased to be a part of a Board of Directors that

is committed to advancing and supporting the professional practice of pharmacists in hospitals and health systems. I can say with confidence that ASHP continues to be a strong and vibrant organization from both a membership and financial viewpoint. With its strong financial resources, and its stellar staff and membership, ASHP is well positioned to meet the needs of the membership.

Figure 1. ASHP condensed statement of activities (in thousands).

	Actual Fiscal Year Ended May 31, 2013	Projected Fiscal Year Ended May 31, 2014	Budget Fiscal Year Ended May 31, 2015
CORE OPERATIONS			
Gross revenue	\$ 41,972	\$ 43,278	\$ 44,905
Total expense	(42,028)	(43,097)	(46,305)
Earnings from subsidiary	1,811	1,425	1,300
Investment income subsidy	102	130	102
Core Net Income	\$ 1,857	\$ 1,736	\$ 2
PROGRAM DEVELOPMENT			
Investment income	\$ 6,784	\$ 2,599	\$ 1,944
Program expenses	(1,459)	(1,658)	(1,704)
Program Development Net Income	\$ 5,325	\$ 941	\$ 240
Programs Funded from Net Assets	\$ (125)	\$ (100)	\$ (400)
Increase in Net Assets	\$ 7,057	2,577	\$ (158)
Pension Plan Adjustment	1,818	—	—
Net Increase in Net Assets	\$ 8,875	\$ 2,577	\$ (158)
Net Assets Beginning of Year	\$ 25,316	\$ 34,191	\$ 35,479
ASHP Net Income	8,875	2,577	(158)
Net Assets End of Year	\$ 34,191	\$ 36,768	\$ 35,320
% of Total Expense	70%	74%	65%

Figure 2. ASHP statement of financial position (in thousands).

	Actual as of May 31, 2013	Actual as of May 31, 2012
ASSETS		
Current assets	\$ 3,504	\$ 3,811
Fixed assets	1,269	1,288
Long-term investments (at market)	45,997	39,110
Investment in subsidiary	5,358	3,691
Other assets	172	434
Total Assets	<u>\$ 56,300</u>	<u>\$ 48,334</u>
LIABILITIES		
Current liabilities	\$ 14,985	\$ 12,968
Long-term liabilities	7,124	10,050
Total Liabilities	<u>\$ 22,109</u>	<u>\$ 23,018</u>
NET ASSETS		
Net assets	\$ 34,191	\$ 25,316
Total Net Assets	<u>\$ 34,191</u>	<u>\$ 25,316</u>
Total Liabilities and Net Assets	<u>\$ 56,300</u>	<u>\$ 48,334</u>

Figure 3. 7272 Wisconsin Building Corp. (ASHP subsidiary) statement of financial position and statement of activities for fiscal year 2013 (in thousands).

	Fiscal Year Ended May 31, 2013		Actual as of May 31, 2013
REVENUE AND EXPENSE		ASSETS	
Gross revenue	\$ 6,950	Current assets	\$ 2,151
Operating expense	4,429	Property and plant (net)	17,973
Operating Income	<u>\$ 2,522</u>	Other assets	2,168
		Total Assets	<u>\$ 22,292</u>
Provision for income taxes	\$ 711	LIABILITIES	
Increase in Net Assets	<u>\$ 1,811</u>	Current liabilities	\$ 1,750
		Mortgage payable	14,613
Owners distribution and capital contributions	\$ (144)	Other liabilities	571
Net Increase in Net Assets	<u>\$ 1,667</u>	Total Liabilities	<u>\$ 16,934</u>
		NET ASSETS	
		Net assets	\$ 5,358
		Total Net Assets	<u>\$ 5,358</u>
		Total Liabilities and Net Assets	<u>\$ 22,292</u>



The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

Recommendations from the 2014 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. Medication Safety Certification

Dan Degnan (IN)

Recommendation: That ASHP continue to work with the National Patient Safety Foundation, the Institute for Safe Medication Practices, and other stakeholders to establish a certification process for medication safety professionals.

2. Revision of ASHP Policy 0610, Pharmacist's Right of Conscience and Patients' Right of Access to Therapy

Nicole Allcock (MO)

Recommendation: That ASHP revise this policy to better support pharmacists not wishing to cooperate with ethically troubling therapies and change the phrase "provide a referral" to "transfer care."

3. Transparency of Manufacturing Source for Medications

Erin Fox (UT)

Recommendation: That ASHP advocate that the product labeling for medications disclose both the manufacturer and the location of manufacture.

4. Removal of Section 7.1 from the Bylaws and Placement into an Appendix or Policy

Brian I. Kawahara (CA)

Recommendation: That ASHP consider removing Section 7.1 of Article 7 of the Bylaws and placing them in an appendix to the Bylaws or a procedural policy.

5. Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs

Wes Pitts (MS), Laurie Warrington (MS), Stephen Eckel (NC), Dennis Williams (NC)

Recommendation: That ASHP develop standardized mechanisms and advocacy to identify and document patients' existing prescription drug coverage and to develop triggers to identify patients for PAPs to optimize care transitions.

- 6. Education About Patient Safety in the Medication-Use Process**
Elizabeth Wade (NH), John Hertig (IN), Dan Degnan (IN)
Recommendation: That ASHP create a task force to assess and develop a guidance document articulating medication safety-related educational needs for pharmacy schools; further to link the core competencies for the medication safety officer role to the pharmacy curriculum and postgraduate training opportunities.
- 7. Safe Use of Drug-Containing Devices and Diagnostic Agents**
Carol Rollins (AZ, ID)
Recommendation: That ASHP affirm that drug-containing devices and diagnostic agents require standards for safe use and monitoring considerations that involve pharmacy issues; further, to advocate that pharmacy departments, in cooperation with other pertinent departments, are involved in decisions related to the safe use of drug-containing devices and diagnostic agents.
- 8. Inclusion of Small, Specialty, Critical Care, and Long-Term Care Facilities in ASHP Practice Surveys**
Lourdes Cuellar (TX)
Recommendation: That ASHP include small, specialty, critical care, and long-term care facilities in all practice surveys so pharmacy directors in these facilities have the same access to practice benchmarks that community and academic hospitals have.
- 9. Manufacturer Labeling of Medication Waste Stream**
Paul Driver (ID), Erin Fox (UT)
Recommendation: That ASHP advocate that manufacturers be required to identify required DEQ waste disposal in the product labeling.
- 10. Risk Assessment of Health Information Technology**
Elizabeth Wade (NH)
Recommendation: That ASHP provide guidance on the specifics of conducting a post-marketing or retrospective assessment of health information technology (HIT); further, that ASHP advocate that vendors be encouraged to make ongoing enhancements to HIT based on safety feedback from hospitals and health systems.
- 11. Medical Marijuana**
Steve Gray (CA)
Recommendation: That ASHP develop policy on the use of medical marijuana in health systems.
- 12. Role of Simulation in Medication Safety in Pharmacy Training**
Dan Degnan (IN), John Hertig (IN), Amy Hyduk (IN), Noelle Chapman (SICP)
Recommendation: That ASHP develop policy on the use of simulation in pharmacy curricula and continuing education for pharmacists training in medication safety.

13. Consideration of Indianapolis as a Summer Meetings Site

Dan Degnan (IN), John Hertig (IN), Amy Hyduk (IN)

Recommendation: That ASHP consider Indianapolis, Indiana as a future site for the ASHP Summer Meetings.

14. Experiential Experiences

Dale English (OH), Megan Swarthout (MD)

Recommendation: That ASHP work with ACPE, academic institutions (colleges of pharmacy), and other key stakeholders to require a portion of experiential education hours to be gained outside traditional work schedules (e.g., typical dayshift hours, Monday–Friday, 8 am – 5 pm) to create a more realistic expectation for the employment environment upon licensure as pharmacists.

15. Preventing Opioid Overdose Through Education and Naloxone Distribution

Roger Woolf (WA), William Jessee (WA), Kathryn Renouard-Brown (WA), Steve Riddle (WA), and Jeffrey Rochon (WA)

Recommendation: That ASHP support the development and implementation of regulations that permit pharmacists and first responders to furnish opioid reversal agents to prevent opioid-related deaths related to overdose.

16. Pharmacist Magnet Program

Darryl Schiller (NJ)

Recommendation: That ASHP create something similar to the Nursing Magnet Recognition Program to recognize health care organizations for quality patient care, pharmacy excellence, and innovations in professional pharmacy practice.

17. Standardization of Doses and Dosage Formulations

Steve Riddle (WA), Kevin Marvin (VT), Julie Zaucha (OH), Tadd Hellwig (SD), Brenda Denson (AL)

Recommendation: That ASHP explore the creation of policy dealing with the standardization of dosing and the need for standardized dosage formulations for medications.

18. RDC and Affiliate Support

Casey White (TN)

Recommendation: That ASHP perform periodic review of state affiliate financial support structure to maintain and foster active participation from state affiliates.

19. ASHP Registration Payment for State Delegates

Vaiyapuri Subramaniam (DC)

Recommendation: That ASHP pay the full registration for all state delegates at the ASHP Summer Meetings in lieu of paying the \$300 per delegate who attend the Regional Delegate Conferences.

- 20. Addition to Rationale of ASHP Policy on Integration of Pharmacy Services in Multifacility Health Systems**
Kristy Butler (OR), Kris Marcus (OR), and Michelle Murray (OR)
Recommendation: That ASHP add a reference to the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive to the rationale of ASHP policy position 1417, Integration of Pharmacy Services in Multifacility Health Systems.
- 21. Publication of Health-System Pharmacy Benchmarking Data**
Elizabeth Shlom (NY)
Recommendation: That ASHP conduct an annual survey of pharmacy department staffing and workload and publish the results in *AJHP*.
- 22. Removal of Allergenic Excipients**
Emily Dyer (VA) and Lisa Deal (VA)
Recommendation: That ASHP advocate manufacturers remove unnecessary, potentially allergenic excipients (e.g., red dye, yellow dye, gluten) from all medications.
- 23. APPE Rotation Holiday on Residency Match Day**
Mark Woods (Past President)
Recommendation: That ASHP work with colleges of pharmacy and APPE practice sites to cancel rotations on Residency Match Day to reduce student distractions.
- 24. Continuing Education on Ethics**
Kathy Donley (OH)
Recommendation: That ASHP develop programming and enduring educational materials on the subject of ethics to improve members' knowledge base.
- 25. Statement on Growth of Restricted Distribution Networks for Prescription Medications**
Richard Demers (PA)
Recommendation: That ASHP develop a statement to minimize the use of restricted distribution networks for new specialty medications.
- 26. Resource Center for Disease Management Guidelines**
Wes Pitts (MS) and Molly Leber (CT)
Recommendation: That ASHP develop a member resource center for disease management guidelines with push notifications that are customizable to alert members when content is updated.
- 27. Including Lot Number in Bar Codes of Pharmaceutical Manufacturer Drug Products**
Lorraine Lee (CT)
Recommendation: That ASHP advocate for pharmaceutical manufacturers to include lot number in the bar code of individual products to the unit dose level.

28. Replacement for ASHP Policy 0914, Education About Patient Safety in Medication-Use Process

Butch Haberber (TX)

Recommendation: That ASHP develop a new policy to advocate that colleges of pharmacy emphasize instruction on patient safety throughout the medication-use process in didactic and experiential education.

29. Election Procedure for House of Delegates Chair

Harold Godwin (Past President)

Recommendation: That ASHP introduce candidates for Chair of the House of Delegates and allow them to present statements at both meetings of the House of Delegates.

30. Guidance Document on Strategies to Curb Prescription Drug Abuse

Nishaminy Kasbekar (PA)

Recommendation: That ASHP work with other key stakeholder organizations to develop a consensus guidance document on strategies to curb prescription drug abuse.

31. Education and Training in Medication Safety

Kristy Butler (OR), Kris Marcus (OR), and Michelle Murray (OR)

Recommendation: That ASHP develop a policy for ongoing CPE on medication safety, similar to ASHP policy 1317, Education and Training in Health Care Informatics Pharmacy.

32. CE Credit for First Meeting of House of Delegates Session

Paul Driver (ID)

Recommendation: That ASHP explore the possibility of providing CE credit for participation in the first meeting of the House of Delegates.

33. Working Group to Address USP Chapter 800

Diane Fox (TX), Julie Nelson (TX), Butch Haberber (TX), Jim Wilson (TX)

Recommendation: That ASHP establish a working group to address issues impacting pharmacy practice when proposed USP Chapter 800 (Hazardous Drugs) is enacted.

34. Risk Assessment of Health Information Technology

Gregory Burger (KS)

Recommendation: That ASHP encourage colleges of pharmacy to include instruction on quality improvement (QI) tools used in the medication-use process in didactic and experiential education, and to support the development of postgraduate, curriculum-based QI process improvement training programs (CE, webinars, conventions) to foster and increase the number of pharmacists with QI process expertise.

- 35. Editorial Change to ASHP Policy 1415, Credentialing, Privileging, and Competency Assessment**
Marjorie Shaw Phillips (GA, on behalf of GA, AL, CA, FL, ID, KY, LA, MD, MT, NE, OH, OR, SD, TX, DC, WI, OK, NH, WY, MO, ME, NV, KS, TN, NC, RI, SC, MS, AK, IL)
Recommendation: That ASHP remove the word “independently” from the third clause of ASHP policy 1415, so that it reads: “To recognize that pharmacists are responsible for maintaining competency to practice in direct patient care.”
- 36. Timely Update of Ordering/Prescribing Databases**
Kevin Marvin (VT)
Recommendation: That ASHP advocate for timely updates of ordering and prescribing medication databases within EHR systems throughout the continuum in support of safe and efficient patient care.
- 37. Statement on the Criteria for an Intermediate Category of Drug Products**
Kevin Marvin (VT)
Recommendation: That ASHP review and update the ASHP Statement on the Criteria for an Intermediate Category of Drug Products to include the safe operational implementation requirements of such a medication category and to identify pharmacist involvement with this category of medications as pharmacist collaborative medication therapy management supporting optimal patient care.
- 38. Revision of ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records**
Jill Bates(SCSS), Christopher Betz (SCSS)
Recommendation: That ASHP revise the Guidelines on Documenting Pharmaceutical Care in Patient Medical Records to strengthen the tone, update the content to support PPMI Recommendations B15 and B6, and promote standardization of documentation practices within the profession to enhance patient care.
- 39. Women in Pharmacy Leadership**
Lourdes Cuellar (TX)
Recommendation: That ASHP develop educational activities and establish a mentoring program to encourage and support the rapidly evolving role of women in pharmacy leadership in hospitals and health systems.
- 40. Cultural Competence and Diversity of Workforce**
Lourdes Cuellar (TX)
Recommendation: That ASHP return ASHP policy 1414, Cultural Competency and Cultural Diversity, to the Council on Education and Workforce Development for revision to recognize the important distinctions between cultural competence and an ethnically diverse workforce.



2014 Report of the President and Chair of the Board

ASHP: Aiming higher

GERALD E. MEYER

Am J Health-Syst Pharm. 2014; 71:1409-13

As I complete my presidential year, I want you to know how much I appreciate the opportunity to have served ASHP and its members as president. I also want to acknowledge and thank everyone here today in the House of Delegates for your ongoing commitment to our organization, our profession, and our patients. You are true leaders in every sense of the word. Your dedication and time, together with the efforts of ASHP's Councils, Sections, Forums, and state affiliates, are what drive this organization forward.

I also want to thank Dr. Abramowitz for his unwavering support throughout this year. On behalf of the Board of Directors, I would like to express our appreciation for the innovative and energetic leadership style he brings to ASHP, which has led to many changes and accomplishments. Thank you, Paul.

In my inaugural address, I mentioned that during my presidential year I wanted to focus on building coalitions, implementing the recommendations of the Pharmacy Practice Model Summit, pursuing provider status, promoting inter-professional education and practice, expanding training and certification for pharmacists and pharmacy tech-

*We are a community of
healthcare professionals
who are focused on
ensuring that people stay
well and patients get well.*



nicians, and positioning ASHP to be as nimble as possible in a rapidly changing environment.

I also mentioned that I wanted to achieve world peace. I'm still working on that one, but I can say that I'm really proud of all that ASHP has accomplished toward these other goals!

Refining ASHP's strategic plan

One of the key ways that ASHP ensures that it is working toward collective goals and objectives is by creating and deploying a robust strategic plan.

One of the top objectives in our strategic plan calls for ASHP to cul-

tivate strong and effective affiliate organizations. And I have an exciting announcement to share with you today. At the ASHP Board of Directors meeting held here just three days ago, we voted to approve affiliation for the Alaska Pharmacists Association Academy of Health-System Pharmacists and the Montana Pharmacy Association Academy of Health-System Pharmacists. This means that ASHP now has 52 affiliated organizations: 1 in the District of Columbia, 1 in Puerto Rico, and, for the first time ever, 1 in every state of the United States. Please join me in welcoming these 2 affiliates to ASHP.

GERALD E. MEYER, PHARM.D., M.B.A., FASHP, is Immediate Past-President, ASHP, Bethesda, MD (gerald.meyer@jefferson.edu).

Presented at the ASHP Summer Meetings, Las Vegas, NV, June 3, 2014.

The author has declared no potential conflicts of interest.

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ASHP's current strategic plan was developed last year by the staff and Board of Directors with the input of Section and Forum executive committee members. The strategic plan prioritizes our work and integrates all of ASHP's activities that we believe will drive improvements in patient care, public health, and practice advancement.

The plan reflects ASHP's vision that everyone should receive safe and effective medication therapy and that this can best be accomplished when pharmacists are present in every medication-use decision made in hospitals, health systems, clinics, and other ambulatory care settings.

To ensure that the plan stays dynamic and relevant, we held a special retreat in April during which board and committee members joined staff to refine the plan so that it continues to meet both member and organizational needs. During the retreat, we discussed healthcare trends and their influence on hospital and health-system practice and on professional policy, member recruitment and retention, and ASHP products and services. We examined the strategic implications of ASHP's recent Ambulatory Care Summit as well as new opportunities presented by increasing hospital and health-system consolidations, the movement of retail chain pharmacies into ambulatory care services, and the growth of specialty pharmacies.

We are now working to update our strategic plan to reflect these and other issues that ASHP must take a lead role in addressing on behalf of our members and the patients they serve.

Pharmacy Practice Model Initiative

Our Pharmacy Practice Model Initiative (PPMI) is now moving into its second phase to include both acute care and ambulatory care. As you know, PPMI envisions pharmacists as interdependent prescribers

who accept accountability for the patient care they deliver. The initiative's recommendations also address the patient care gaps that we know exist today.

It is such an exciting time because practice is evolving and "aligning" with many of the Pharmacy Practice Model Summit's recommendations. These recommendations are entwined within all of ASHP's major initiatives, from the strategic plan to our efforts to grow pharmacists' footprint in the ambulatory arena to our advocacy for provider status.

During the past year, ASHP's Center for Pharmacy Practice Advancement has continued to augment member resources and services that are related to the PPMI. We've witnessed increasing adoption of the Hospital Self-Assessment (HSA) tool¹ at hospitals across the country. As of today, more than 1400 hospitals have taken the assessment.² State affiliates continue to have a significant influence in this area. More than 50% of hospitals in six states have completed the HSA. Let's give a shout-out to Maine, New Hampshire, Rhode Island, South Carolina, Wisconsin, and Washington.² A self-assessment for ambulatory practice should be available later this year.

I hope that all of you noted the progress of the PPMI National Dashboard on the ASHP website.³ I'm happy to report that we are seeing overall progress, with two goals that were standouts. Goal number one (that pharmacist roles, practices, and activities will improve medication use and optimize medication-related outcomes) and goal number four (that pharmacy departments utilize available automation and technology to improve patient safety and efficiency) both saw impressive gains this year.

I also want to update you on the progress toward the development of a Complexity Score to help hospitals identify the patients at greatest risk for preventable adverse drug events.

We envision that the Complexity Score, sponsored by the ASHP Research and Education Foundation, will be used to allocate pharmacists' finite resources where they are likely to have the greatest impact.

The Foundation has contracted with renowned researchers at the University of Florida who are completing the development and initial testing of the Complexity Score. During the next year, these researchers will test the score in hospitals across the country.

Privileging and credentialing

In recent years, the number of board-certified pharmacists has grown from 3,600 in 2002 to more than 19,000 in 2014.⁴ The growth of board certification is due, in large measure, to ASHP's longstanding efforts through its policies, services, and professional practice initiatives. But the efforts of our members—who are dedicated to the highest level of practice—have been the greatest driver of this trend.

ASHP is committed to exploring and implementing new specialties and creating a sound process for developing new specialty credentials.

We believe that credentialing and privileging are poised to expand dramatically as care shifts toward a team-based approach with a focus on accountability and affordability. ASHP believes this is such an important issue that we have reflected the need for credentialing and privileging for advanced patient care roles in many of our initiatives, including our Pharmacy Practice Model Summit recommendations, and in our policies.

As the leading provider of continuing pharmacy education in the United States, ASHP offers specialty review courses, recertification programs, and core therapeutic modules to help practitioners prepare for Board of Pharmacy Specialties (BPS) exams in pharmacotherapy, ambulatory care, and oncology.

In partnership with the American College of Clinical Pharmacy, the American Pharmacists Association, and the Pediatric Pharmacy Advocacy Group, ASHP helped lead the petition efforts that resulted in BPS approval of pediatric and critical care specialties last year. And I'm excited to report that ASHP will be conducting pediatric and critical care specialty review courses before the 2015 Summer Meetings.

In the new world of healthcare, enhanced credentialing and privileging will be the norm, not the exception. ASHP will remain at the forefront of that movement.

Task Force on Organizational Structure

As you know, we continually work to be responsive to the challenges our members face and the needs they have. One of the ways we do that is to periodically review the Society's governance, policymaking process, and membership structure.

Thank you for your vote to amend ASHP's governing documents as recommended by the Task Force on Organizational Structure. These changes will help us to meet the needs of a changing membership.

So, how might the policy process change? In the future, we will have the ability to hold virtual House meetings. And members will have many more opportunities to contribute to the policy process throughout the year. Also, it is possible that future ASHP presidents might provide this report via hologram.

Safe medication use

Compounding. The New England Compounding Center tragedy has faded a bit from front-page news; however, the issue of ensuring sterile compounding has not. Since the 2011 outbreak of fungal meningitis, ASHP has been at the forefront of national efforts to tighten oversight of compounding manufacturers while strongly advocating for the ability

of hospitals and health systems to continue their own compounding practices.

From repeated public testimony in Congress to ongoing discussions with the Food and Drug Administration (FDA) to a massive media campaign that reached millions of consumers with messages about pharmacists' role in safe compounding . . . ASHP became *the* national voice on safe compounding practices.

That advocacy paid off in November 2013, when President Obama signed the Drug Quality and Security Act.⁵ The new legislation clarifies federal oversight of compounding practices and establishes a voluntary system that outsourcing manufacturers can use to be inspected by FDA.⁶ It also contains provisions for tracking pharmaceutical products throughout the supply chain and puts into place a single federal standard that supersedes state laws.

The new law is certainly not perfect, but it represents an important step in ensuring the safety of products prepared and sold by outsourcing facilities. This is a real win for patients, and I want to acknowledge the significant effort undertaken by ASHP staff members and the support of all ASHP members to get this passed.

Drug shortages. ASHP continues its advocacy on behalf of patients and our members in the area of chronic drug shortages. We know that this issue is an ongoing source of difficulty and stress for many practitioners, and we have been actively engaging FDA in discussions about how current shortages of i.v. fluids are posing real health risks to patients. The agency is trying to help manufacturers who make these critical medications return to the production of volumes that meet the demand as soon as possible. ASHP continues to update members as the situation evolves.

We are in ongoing discussions with stakeholders to evaluate eco-

nomics and other factors that contribute to shortages and to seek solutions. In fact, if you want something interesting to read on the plane back home, take a look at the recently published report from the 2013 Drug Shortages Summit, entitled "Evaluating Long-Term Solutions."⁷ Stay tuned for more, because the summit participants are meeting again in August to continue our important work in this area.

Working with the University of Utah Drug Information Services and stakeholders like the American Hospital Association (AHA), ASHP created a new guidance document for members in March that outlined conservation strategies for large-volume i.v. fluids.⁸ We also released the results of a survey of pharmacy directors showing that these shortages are affecting more than 75% of U.S. hospitals and other healthcare settings.⁹ We used the survey results to provide context for the public during our media outreach about this difficult patient care issue.

Antibiotic stewardship efforts. In the realm of safe medication use, we are all well aware of the overuse of and growing resistance to many classes of antibiotics. Toward that end, ASHP has been working on a number of antibiotic stewardship efforts.

We partnered with a number of organizations, including the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America, on the stewardship-education.org website. The site is designed to increase the competencies of healthcare teams that are charged with improving antimicrobial use within their institutions.

We are also collaborating with AHA to develop a toolkit that will be released soon. Various clinical guidelines, including revisions to a statement on vancomycin monitoring, are in development.

Finally, we are supporting the federal Antibiotic Development to

Advance Patient Treatment Act,¹⁰ which will incentivize and streamline the development of new antibiotics to treat serious or life-threatening conditions.

It's critical that the public understand issues surrounding pharmacists' role in safe medication use. So, we continued our public relations efforts this past year to educate patients and other stakeholders.

ASHP spokespeople, including many members, conducted hundreds of media interviews throughout the year on the issues I've just covered as well as pharmacists' changing healthcare roles. These interviews led to stories in more than 500 media outlets in which ASHP was mentioned. As such, we reached more than 6 million consumers with messages about pharmacists' role in safe medication use in media outlets such as *The New York Times*, *Chicago Tribune*, and ABC News.

Accreditation

You may remember that last year marked the 50th anniversary of ASHP accreditation of pharmacy residency programs and the 30th anniversary of ASHP accreditation of pharmacy technician programs.

ASHP remains focused on growing the number of residents and residency programs across the country. To help lead those efforts, ASHP Past-President Janet Silvester was hired as the new vice president of accreditation services in 2013. With more than 30 years of experience in hospital pharmacy leadership, Janet is eminently qualified to expand ASHP's accreditation efforts.

Our work to grow residencies can be seen in the numbers. As of April, there were 1720 ASHP-accredited residency programs in the United States, an increase of 129 programs from last year.¹¹ And in 2014, we saw the creation of 269 new residency positions. In the past four years, there have been nearly 900 additional

residency positions offered in ASHP-accredited programs.¹¹

Although these numbers are impressive, ASHP continues to work hard to grow residency capacity. We are covering all the bases with new training programs on how to start and expand residency programs, a new preceptors' skills resource page on ashp.org, Web-based education about ASHP's new and existing accreditation standards, educational programming at ASHP meetings, and a new video about the importance of pharmacy residencies. We are also working to streamline the accreditation process.

We know that one of the continuing challenges for students seeking a residency is the actual number of positions available across the country. I want to assure you that ASHP is focused on closing that gap by fostering the availability of more residency positions.

Our goal is to ensure that, in the future, every student who is seeking a residency will be able to find one.

As you know, pharmacy technicians play key roles in today's healthcare environment. Having a work force of technicians with the proper training and knowledge is critical.

Earlier this year, ASHP joined forces with the Accreditation Council for Pharmacy Education to create a joint approval process for accredited pharmacy technician training programs. This historic collaboration resulted in the creation of the Pharmacy Technician Accreditation Commission (PTAC).

PTAC, which will ensure and advance the quality of technician education and training programs, will meet for the first time in August. We are very excited about this next chapter in technician accreditation.

Presidential pardon

As I enter the waning moments of my presidential term, I offer the following presidential pardon.

Recognizing that there are colleagues who have previously professed that (1) pharmacists working in different practice settings would never work together toward a common vision of practice, (2) pharmacy organizations would never work together to advance the practice of pharmacy, and (3) Congress would never consider legislation to recognize pharmacists as healthcare providers, *I hereby issue this presidential pardon of all pharmacist naysayers*. Further, I welcome them to join their 43,000 colleagues as members of ASHP, who are working to envision, promote, and implement a future of pharmacists advancing healthcare.

Conclusion

Before I conclude my remarks today, I want to remind you of two additional ways you can help ASHP advance our mission. Please consider contributing to the ASHP Research and Education Foundation and the ASHP Political Action Committee. Both of these organizations help us to make a difference for our patients and our members as we work to advance practice and advance healthcare.

Although what I've reported on here today are just some highlights of the past year, it should give you some insights into our priorities and the many ways in which ASHP is working to support you and all of our 43,000-plus members.

Your work—the sacrifices you've made within your professional life and at home in order to be here this week—is critical to our success. The discussions and policies that emanate from this House are essential to ASHP's drive to expand patient care roles for pharmacists and improve medication use for all patients.

We are a community of healthcare professionals who are focused on ensuring that people stay well and patients get well. I hope that you are

as proud as I am to call ASHP your professional home.

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2014 Report of the Chief Executive Officer

ASHP is constructively dissatisfied

PAUL W. ABRAMOWITZ

Am J Health-Syst Pharm. 2014; 71:1414-7

Good afternoon and welcome. It is my pleasure to be with you today to share some of the past year's initiatives to improve patient care and advance pharmacy practice. Let me first start by thanking all of you—our members and leaders—for the great work that you do each and every day on behalf of your patients and the profession of pharmacy. ASHP is your professional society, and everything we do is done for you and with you.

I also would like to ask ASHP-affiliated state society elected officers and executives to stand. The role you play in advancing ASHP's national priorities at the state and local level is so important. Please accept our heartfelt thanks for your stellar efforts.

Next, I would like to recognize my predecessor, Dr. Henri Manasse, who is with us today. Henri, please stand. And his predecessor, Dr. Joseph Oddis, while he could not be here today, sends his sincere best wishes from Bethesda.

President Meyer, allow me to thank you for a year of exceptional leadership on and engagement in some of the most important issues to face ASHP and the profession of pharmacy in many years. We are making history, and you have been a central part of all that we have

ASHP is constructively dissatisfied, and we will be working with extreme focus and steadfast resolve to ensure that pharmacists obtain provider status in the coming years; to advocate the role of pharmacists in improving patient outcomes throughout the entire continuum of care; and to provide resources that best meet the needs of our membership.



achieved this past year. Let's give Gerry a round of applause for his leadership as the president of ASHP.

Finally, I would like to thank the ASHP staff. You are truly the best in the business!

Did I miss anyone? I missed my wife, Jan! Thank you, Jan.

This year has been one for the record books. From launching a major coalition representing all of pharmacy and introducing federal legislation for pharmacist provider status, to achieving consensus at our landmark Ambulatory Care Conference and Summit,¹ and to attaining enhanced collaboration with medicine, nursing, and a wide array of other stakeholders, this has been a

busy year. I am certain that when we look back, 2013–2014 will be viewed as a year to remember.

New ASHP brand

The founder and former chief executive officer (CEO) of UPS, Jim Casey, was famous for using the phrase “constructive dissatisfaction.”² To me, this simply means never being satisfied and always being positive while looking for ways to improve while supporting an organization—or in our case, a profession—for what it has accomplished and what it does well. I believe that constructive dissatisfaction typifies how ASHP and our members approach healthcare.

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ASHP's new vision that "medication use will be optimal, safe, and effective for all people all of the time"³ is an example of how ASHP is constructively dissatisfied with the status quo and is pushing the limits to achieve what before may have seemed impossible. This simple, far-reaching, and bold vision makes it known to all that ASHP is first and foremost focused on the patient. The new vision is central to every activity that ASHP undertakes, and it reflects our core belief that pharmacists are patient care providers who improve outcomes throughout the entire continuum of care.

During yesterday's opening session, we introduced the new ASHP logo and tagline⁴ to you. This change represents so much more than just a change in our symbol. It exemplifies a constructive dissatisfaction and drives home a vision for what the future can be for ASHP. It represents the fact that ASHP is a changing organization that is looking to the future of how healthcare will be delivered. More importantly, it recognizes that ASHP members are patient care providers who serve on healthcare teams in acute and ambulatory care settings throughout the entire continuum of care. It also recognizes that ASHP is a strong and compelling brand in the minds of our members, our patients, the public, and a wide variety of other stakeholders.

Yesterday's introduction of the new logo and tagline was just the start of a broader initiative that will reflect the 21st century version of ASHP. I hope you share our excitement about these changes. To experience the full effect of our new ASHP logo and tagline, make sure to attend the upcoming ASHP Midyear Clinical Meeting in Anaheim where they will be front and center throughout the meeting.

Ambulatory care

I mentioned our Ambulatory Care Conference and Summit, but

let me also say that it is wonderful to see how many pharmacists today are serving as patient care providers in our clinics, large and small. I am amazed when I think back to the mid-1980s, when it was clear that there was an unmet need for more pharmacists to serve patients in a comprehensive fashion in clinics. Fast-forward to today where ambulatory pharmacy practice models are flourishing, and many more patients have the access they deserve to the patient care services of pharmacists. What wonderful progress we have made over this span of time. This evolution in pharmacy practice represents another example of constructive dissatisfaction with the status quo by ASHP's members.

Today's healthcare system creates a greater demand for ambulatory care services by creating new team-based delivery models and payment systems such as accountable care organizations. Today the incentives are changing in ways that make the case to have pharmacists on the team even more compelling. We all know that at the end of the day when pharmacists are on the team, health outcomes are better, patients are safer, and healthcare costs are lower.

It also probably comes as no surprise that pharmacists who care for patients in ambulatory care settings represent one of the fastest growing segments of the ASHP membership. I am so glad that ASHP had the foresight 20 years ago to create the precursor of our Section of Ambulatory Care Practitioners, originally called the Section of Home Care Practitioners, and that today ASHP has an extremely comprehensive array of services for ambulatory care pharmacists.

The Ambulatory Care Conference and Summit held in March of this year was a spectacular sold-out event that brought together practitioners to create a shared vision and series of forward-looking recommendations on ambulatory care pharmacy

practice models. This summit was part 2 of the 2010 Pharmacy Practice Model Summit that focused on acute care. The Ambulatory Care Summit resulted in 25 high-impact consensus recommendations that call for pharmacists to be central members on all ambulatory care patient care teams and also described the types of qualifications and scopes of practice that need to exist in order to optimize the pharmacist's role on behalf of our patients.

ASHP has big plans for new tools, resources, and advocacy aimed at achieving the recommendations from the summit. I hope you will continue to follow these new developments in the ambulatory care arena through the work of the ASHP Section of Ambulatory Care Practitioners, the Ambulatory Care Resource Center on our website, and all of the education we will be providing at ASHP's meetings. Speaking of meetings, we are also happy to announce that we will be adding an ambulatory care conference to next year's Summer Meetings in Denver and in future Summer Meetings as well.

Provider status

I often mention that pharmacists are patient care providers and that pharmacists are absolutely essential members of every interprofessional team. With that in mind, we still have barriers to pharmacists realizing their full potential. And one of the biggest barriers is that the Social Security Act, in which the Medicare program resides, does not recognize pharmacists as providers. Well, I stand before you today to say that with your help, ASHP and its partners plan to change that. ASHP is constructively dissatisfied, and we will be working with extreme focus and steadfast resolve to ensure that pharmacists obtain provider status in the coming years. Our patients have waited way too long!

In January 2014, the Patient Access to Pharmacists' Care Coali-

tion was formed.⁵ The goal of the coalition is to fulfill an unmet need by increasing access to the patient care services of pharmacists. The coalition is going to achieve that by working with Congress to amend the Social Security Act to recognize pharmacists as providers.

The coalition represents almost all national pharmacist and pharmacy organizations in the United States. These include ASHP, the American Pharmacists Association (APhA), the American Association of Colleges of Pharmacy, the American Society of Consultant Pharmacists, the National Association of Chain Drug Stores, the National Alliance of State Pharmacy Associations, and the National Community Pharmacists Association. Further, it includes independent and chain pharmacies, wholesalers, and a growing number of nonpharmacy stakeholders. We are also working to bring physician, nursing, consumer, and patient groups; business coalitions; individual hospitals and health systems; and many others onboard in support of the coalition's goal.

The coalition was successful this year in advocating for the introduction of H.R. 4190, which is a bipartisan bill currently with 39 congressional cosponsors—and that number is growing every day—that will recognize pharmacists as providers in the Social Security Act who are working within their state scope of practice in medically underserved areas.⁶ This is a great step in the right direction, and we believe a companion bill in the U.S. Senate is just around the corner.

I would like to address a few important aspects of the bill. First, I want to address medically underserved areas. Medically underserved areas represent a large part of the United States and include urban and rural areas, as you can see on the map shown behind me. All Medicare beneficiaries who reside within a ZIP code designated as underserved

would be eligible. These areas also represent places where there is often very limited access to various health-care providers.

Second, I would like to talk about qualifications and credentials. Just like for physicians and other health-care professionals, H.R. 4190 leaves it to the states to determine the scope of practice of pharmacists and what qualifications and credentials are required to perform certain patient care services. Also, just like for physicians and others, H.R. 4190 provides latitude to healthcare organizations to use their privileging and credentialing processes to determine what practitioners can and can't do.

I call on you to support ASHP's and the coalition's efforts to achieve provider status for your patients and for your profession. We need you to continue to reach out to your elected officials in Washington, D.C., to tell them your story about how you make a difference in the lives of patients and how provider status would help. Our teams in government and affiliate relations stand ready to help you every step of the way.

A significant number of states have provider status already or are working hard to gain it. The patients and pharmacists in these states will be extremely well positioned to benefit from pharmacists being recognized as providers at the federal level. We need more grassroots efforts like these in every state to ensure that patients everywhere can benefit from the vital services we provide. I thank you for working with ASHP to achieve provider status.

Relationships and partnerships

Part and parcel to all that we do at ASHP and all that you do in your practice is building relationships. At ASHP, that means building strong relationships and partnerships with medical, nursing, hospital, consumer, and pharmacy associations. It also means developing and enhancing

relationships with accreditation bodies, lawmakers, government agencies, and many others.

I am very pleased with the exceptional relationships we have with our colleagues in the other national pharmacy organizations. I am especially happy about the partnership we have with APhA to work together on a host of professional and public health issues. I want you to know that the two largest pharmacy professional associations are constantly seeking ways to work together in the best interest of patients.

This year we were also fortunate to have expanded our relationships with groups such as AARP, the American Hospital Association (AHA), the American Nurses Association, the American College of Physician Executives (ACPE), and the Pew Charitable Trusts.

We recently entered into a joint agreement with ACPE, which includes its cosponsorship of our Medication Safety Collaborative this year. ACPE's members include physicians who serve as CEOs, chief medical officers, vice presidents of medical affairs, medical directors, and other physician leaders. We are also printing joint publications in one another's journals and will be conducting educational programs at our respective meetings, which are intended to help shed light on how much we have in common as pharmacists and physicians and what each group brings to the table.

I am also pleased that our good friends at the Society of Hospital Medicine are also serving this year as cosponsors of the Medication Safety Collaborative.

I was recently invited to serve on the board of trustees of the American Nurses Foundation and am impressed about how enthusiastic they and the American Nurses Association are about working with ASHP. We have had some preliminary conversations about forward-thinking ideas that I am confident

will lead to mutually beneficial advances in our respective professions and will improve healthcare in this nation.

The Center on Pharmacy Practice Accreditation (CPPA), a partnership among APhA, the National Association of Boards of Pharmacy, and ASHP, continues to be developed as an accreditation body, led exceptionally well by ASHP Past President Lynnae Mahaney. CPPA now has an accreditation standard in community pharmacy⁷ and is currently completing work on a specialty pharmacy standard. We are also in talks with a number of potential partners about other areas of practice where there is a need for an accreditation standard. I am very happy to report that CPPA recently accredited its first two programs under the community pharmacy practice standard: Johns Hopkins Outpatient Pharmacy in Baltimore and Goodrich Pharmacies in Minnesota. These pharmacies are accredited for the full scope of patient care services that they provide.

Another great partnership that expanded this year was our relationship with the Academy of Managed Care Pharmacy (AMCP) when we convened a transitions-of-care work group in March that focused on identifying solutions to create a more seamless and reliable medication-use process throughout transitions of care. We look forward to publishing a summary of that discussion later this year, and to continuing to work with AMCP to create a better healthcare system. We are also very pleased to have partnered with the American Council for Pharmacy Education to establish the Pharmacy Technician Accreditation Commission, which will serve as the preeminent accrediting body for pharmacy technician education programs.⁸

A great friend of ASHP is AHA, and we work with them on a regular basis. This year we have focused much of our joint discussions on drug shortages, pharmacy com-

pounding, the 340B drug discount program, and provider status. This open line of ongoing communication with AHA is vital to achieving many of ASHP's strategic interests and serves as another example of the power of partnerships.

I am also committed to maintaining strong relationships with our ASHP affiliates. Since we met last June, I have visited affiliate meetings in Mississippi, Virginia, Rhode Island, Vermont, and Texas. And since I have taken this position as CEO, I have attended a total of 14 of our state affiliate annual meetings, and I will continue to visit the others. I really value these opportunities to meet with members and confirm our strong commitment to our affiliates. I also make the point to visit local practice sites wherever I'm traveling. I'm always inspired by these visits, seeing our members' innovative patient care services first hand.

Conclusion

As I conclude my remarks, I hope you can see that ASHP is doing so much to help you improve the lives of your patients. I am so proud of the accomplishments of this great organization, and I want you to know that we attribute the success of ASHP to you—our members.

Every CEO at some point in time says that we are experiencing an unprecedented amount of change and that the opportunities have never been greater, but as I stand here today and reflect on this past year and what is before us, I truly believe that. Whether it's provider status, the new logo and ASHP brand, the great partnerships we have forged, the success of our affiliates, or the rapid growth in ambulatory pharmacy practice, this is a great time to be a pharmacist.

My good friend and former president of ASHP, Roger Anderson,⁹ said in his 1987 inaugural address "make no small plans." That statement has stood front and center in my mind

to this day. I believe it exemplifies ASHP's willingness and approach to tackling the most difficult and vexing issues that face our profession and to identifying innovative solutions to advancing patient care and moving the profession forward. Roger, thank you for that sage and principled advice.

Thank you all so much for joining us for the ASHP Summer Meetings and for being an ASHP member and part of this House of Delegates. I am looking forward to continuing to work with you with a strong sense of constructive dissatisfaction throughout the next year to achieve some of pharmacy's biggest and most important goals. Thank you very much.

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Inaugural address of the Incoming President

The constant in the patient care equation

CHRISTENE M. JOLOWSKY

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I am excited to be here today and for the opportunity to serve as ASHP's president.

We all know that journeys like this are not made alone. So, at the very outset, I would like to thank my peers, mentors, work colleagues, family, and pharmacy friends for being there with me and for me. You know you all mean a lot to me.

And a special shout-out to the ASHP staff, who I have gotten to know well these past years.

I have a few specific people to mention, and I am so thrilled that they are able to be here today.

My three sisters—Terry with her husband, Ken; Ellie with her husband, Scott; and Julie who is here with her husband, Marty, and their daughters, Sandy and Sam. Although my older brother Steve couldn't be here today, I know that he supports me fully.

Also here today are my in-laws Eileen and Allen Jolowsky; my husband's sister, Jeri, and her husband, Lloyd, and their children, Brianna and Jared; and my cousin, Jackie!

My parents are gone, but I know they are here in spirit. They were always very proud of me and my

As we make important decisions about policies, therapies, and what the future of pharmacy should be like, we must ask ourselves, Are we fulfilling our role as the constant in the patient care equation?



brother and sisters and our accomplishments, and today is no exception.

Last, but obviously not least, I want to thank my husband, Mike, and my lovely daughters, Claire and Nora, who mean so much to me. You are my joy, my rock, and my sanity when things get hectic.

The Cheshire Cat

Today represents the chance to share my point of view and philosophy, to let you know a little about who I am, and to promote ASHP.

In preparing this speech, I turned to the wisdom of a favorite author from childhood, Lewis Carroll, who wrote one of my favorite books, *Alice's Adventures in Wonderland*.

Carroll's writings are known to be a little quirky but also thought provoking. I'd like to share a conversation between Alice and the Cheshire Cat that I think is quite instructive for us, as pharmacists today:

'Would you tell me, please, which way I ought to go from here?'

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‘That depends a good deal on where you want to get to,’ said the Cat. ‘I don’t much care where’—said Alice. ‘Then it doesn’t much matter which way you go,’ said the Cat.¹

This brings me to the question for us to think about today: Where are we going, as pharmacists, as a profession? This question is followed by two more: How should we get there? And who do we need with us along the way?

Where are we going?

Unlike Alice, we care very much about where we’re going.

My destination—and from talking to my colleagues, I understand it’s your destination, too—is recognition for the value and the work we do as pharmacists, recognition through provider status, to validate pharmacists as full members of the patient care team.

So if provider status is the “where,” how will we get there?

We can best build a road map by paying close attention to the landmarks we need to hit along the way. What are the basic requirements for patient care? What are the practice models and patient care marks we need to pay attention to?

Of course, if we just want to get “somewhere” near provider status, then we can afford to wander around a bit. But that is not our goal. “Somewhere near” isn’t close enough for us or for our patients.

Solving for x

We have a very clear destination in mind: better patient care and more recognition for the value we bring as medication experts, which means we must be very deliberate and strategic about the steps we take to get there. Advocacy will be a key part of our success, and ASHP plays a crucial role in this.

The Society is helping to create a road map that we can navigate together. Even if we are traveling at dif-

ferent speeds, we must all be heading in the same direction.

To do this, ASHP is being guided by the expanding practice in ambulatory care, identifying new practice models, and creating tools to get us to our destination. But first, let me give you a little background about myself.

I mentioned earlier that my parents are no longer with us. But as with all parents, they shaped who I am. And their guidance helped to shape the pharmacist I’ve become.

There are three main values that my parents instilled in me and my siblings. The first was the importance of getting involved and helping others. These were not just words to them. They really lived it. Both of my parents were active in the community. My father gravitated to leadership positions, especially within the American Legion. My mother didn’t want her name in lights, but she rolled up her sleeves and helped wherever it was needed. Her mantra was, “You’re here, make yourself useful.” My brother and sisters and I learned the importance of leadership and service as well as the value of participation and teamwork.

Second, my parents shared their true passion for getting involved and the important role that passion plays in our work. If we are passionate about something, we will be motivated to get involved and stay involved.

And, third, they always stressed the importance of education. All of us kids knew we were going to college—it was not even an option! This instilled in us the passion for lifelong learning and growth, which is why I always made sure I was available to help my girls with their homework (whether they liked it or not). And math was where I could help them the most. But this presented some challenges, because math when my kids were little was taught differently than how I learned it! Yet the math problems are still the same even if we approach them in different ways, right?

We had to get on the same page if I was going to help them understand these complex math problems without too much frustration. For me, math could always be distilled to small, simple equations. In each equation, there is always some constant, some variable, and some element that is missing. And we are all familiar with “solving for x .”

I was thinking about the different approaches to math problems, and I started to look at my professional life through this same prism. My first thought was to “solve for what’s missing.”

Solve for x . What does that mean for pharmacy practice? Well, during a recent intraprofessional meeting, we discussed who the members of the healthcare team are and their roles. I looked at the participants and started wondering who was missing. Who else should have been there? Who needs to be present to learn from what we are doing? And how do we bring our value, as pharmacists, to those people who were not in the room?

The same could be asked from an organizational perspective for ASHP. As we continue to advance practice across the continuum, who needs to be at the table? Are we fully engaging our members? Potential members? Students? Pharmacy technicians? And other stakeholders?

What else do we need to do to make sure we are connected with each other within ASHP, as well as with external stakeholders, to be most successful in moving practice forward?

In my work at the college, I talk to students all the time. They often ask me about how I got involved with ASHP. I share the decisions I made as my career developed to follow my passion for advancing practice.

I stress the value of networking with peers and potential mentors. And I emphasize the importance of tapping into the knowledge and expertise of those around you. These

are all values that lead us where we want to be.

This brings us back to Alice in Wonderland: If you don't know your destination, "Then it doesn't much matter which way you go." It is the involvement, the sharing, and the passion that helped define that destination for me.

New pharmacy equation

So all of this thinking about life in the context of math problems brings me to this new equation:

$$(\text{Pharmacist involvement in } x) \times \text{passion} = \text{better patient care and more recognition of pharmacists' value}$$

In solving this equation, we are faced with many variables:

- Grassroots advocacy efforts,
- Support from decision-makers,
- Recognition from payers,
- The need for quality improvement, and
- The need to follow patients along the entire continuum of care.

There are also other constants in our equation: the strength of our practitioners, including new and future pharmacists, and advanced clinical practices.

What other information is missing in order to solve the equation?

- Recognition as providers?
- A common understanding of the value of pharmacists?
- The need to continue to advance our knowledge and training?

All of these variables, once figured out, multiplied by passion make this equation solvable!

Pharmacists as the "constant"

Let's take this to another level. I believe that pharmacists are the constant in the patient care equation. We are present in every care transition and practice setting.

Not too long ago, pharmacists' approach to care was focused on the patients when they were in front of us. But that didn't take into account what was going on in the whole life of our patients. Often, we didn't have that information.

But today, our focus is on the whole patient and his or her entire life along the full continuum of care. This is going to shift our mindset regarding patient care. Our patients are no longer "snapshots in time" as they come in and out of our care.

We were accustomed to handing our patients off to practitioners in other healthcare settings. But increasingly we are *in* those other settings. We need a consistent patient care delivery model that includes discharge planning and follow-up care for patients—a model that extends from the hospital to long-term care to ambulatory care clinics and back, as necessary.

And what are we doing at ASHP to support this? ASHP is focused on achieving provider status, working at the state level to expand our scopes of practice, and growing its tools and resources to help us become better practitioners.

Now some of these settings may represent environments with which we are not familiar. Yet this is exactly where our value is amplified, by working with other members of the healthcare team.

Pharmacists as the constant in solving patient care problems provided me with a new way of thinking about my own career. I served in leadership positions in health-system pharmacies for more than 25 years. Early in my career, I knew that I wanted to be in a position that would create change. And it was clear that leadership roles would provide me with that opportunity.

One of the things I especially enjoyed is organizational management—figuring out what works to improve patient care and safety and what doesn't, whether it had to

do with education, engineering, or technology.

How does my career path, which took me in a direction I did not originally foresee, reconcile with my imperative today that we must keep our destination in mind? It demonstrates that we must be open to adjusting the path to get to our destination.

At my college, I find that students are certainly focused on their destinations—graduating, residencies, finding their first jobs, and making themselves marketable—all of which are understandable.

Yet in their rotations and their residencies, I encourage these students and new practitioners to focus on the skills they are learning, which will serve them well into the future. That's why I am very passionate about promoting residency training, because it provides a positive and supportive environment that fosters the critical thinking and decision-making skills that are needed in pharmacists today.

Likewise, ASHP is working hard to expand residencies² and support board certification,³ understanding that these skill sets will help students stand out in their future careers and provide a framework for employers to see what is special about them as individual practitioners.

Solving the problem

So let's go back to the time I sat at the table helping my daughters Claire and Nora with their math homework. When we want to solve our professional pharmacy problems, we need to ask the same questions that I asked my daughters:

- What is the value that we are given?
- What is the known entity or constant in the equation?
- And what (or who) is the missing element in the equation?

To solve the problem, I hope I have you thinking about the value of the role of pharmacists. We have

to establish ourselves as the constant in the equation. That means we must have a handle on some big concepts, such as

- What are the needs of the patient?
- Where is the pharmacist?
- What are the gaps in our care delivery system?

This equation analogy continues with finding the missing element. What, or, in our case, who, is missing from the equation? Ask this question as you participate in the meetings here this week. We have the Medication Safety Collaborative, the Informatics Institute, and the Pharmacy Practice and Policy meetings.

Look around while you are in these meetings, and ask yourself, How can we reach out to people who are unable to attend and connect them with the rich content of the meetings? There are people who need to be here so that they can benefit from the great information and networking that are available. Are we doing all we can to bring them into the equation?

Specifically, where are the students, residents, preceptors, fellow colleagues (maybe from different practice settings), staff pharmacists, and technicians? There is value here for them all:

- Value in participating, or even simply observing, our policy process through the House of Delegates,
- Value in hearing the inspirational words from our Whitney award recipient and ASHP Past-President John Murphy,
- Value in the education that's offered here this week, and, of course,
- Value in the unique networking opportunities.

And you can ask these same questions about ASHP. How do we involve more pharmacists as members? How do we involve more ASHP members in the organization's ac-

tivities and initiatives so that they get the full value of belonging to ASHP? You truly only get out of membership what you put into it. We need to encourage more members to be fully engaged so that they get the most value from their membership.

And let's keep going with this part of the equation. Who is missing from our practice experiences? Are all of the stakeholders accounted for? What about the patients and their caregivers? Are we including them in the decision-making for their own care?

What about our own administrators, and regulators, and legislators—both local and national—who hold so much sway over what we can do and how we do it? We need to make sure that all missing elements are solved for and in place. That way, we'll be able to work together to achieve the best outcomes for our patients.

Clearly, this is a complex, seemingly endless equation that few have actually solved. We are still working on it! It is critical that we do not give up on this one.

As we make important decisions about policies, therapies, and what the future of pharmacy should be like, we must ask ourselves, Are we fulfilling our role as the constant in the patient care equation?

When decisions are being made about medication use in our practice settings, are we present, visible, and easily available wherever the patient is? In today's healthcare environment, we need to focus on the patient's care across the entire spectrum. The days of treating patients for a few days in the hospital and waving goodbye with best wishes as they leave clutching their prescriptions are over.

Equivalent equation

All of this brings me to another equation I want to share with you today. It's an equivalent equation:

The future of ASHP = the future of practice

As I start my presidential year, I am absolutely thrilled with the direction of ASHP. There is so much to be excited about:

- Our new mission,⁴ vision, and strategic plan,⁵ which focus on all patients and all aspects of care,
- The Pharmacy Practice Model Initiative (PPMI),⁶ including its recent work in the ambulatory care arena,
- Our efforts to achieve provider status,
- Our new brand and logo,⁷ which represent us as a contemporary, strong, forward-thinking organization,
- Our growth in members, which means that more and more practitioners are finding the value of being part of ASHP,
- Our work to help members manage critical practice issues like drug shortages⁸ and compounding,⁹
- The tools and resources ASHP creates to help us in our daily practice, and
- ASHP's work to partner with others to further our influence on public health policy and advance your role as healthcare providers.

Where are you in the pharmacy equation?

So let's go back to my first pharmacy equation. First, I want you to ask yourself: How do I fit into the equation? Are you the constant of the patient care equation in your work site? And what about your professional associations? Are you fully engaged at the state and national levels? There are so many ways to get involved to advocate for your patients, advocate for change, and improve your patient care setting.

One great way to do that is to make your presence known on ASHP Connect,¹⁰ the organization's social network, where you can contribute to professionwide discussions about critical practice issues. Always ask yourself, "How can I share my knowledge, experience, and wisdom with others to improve their patient care practices?"

Next, make sure you know where you are going! Find your path, and adjust it as needed. When I started my career, I didn't set out to lead key professional initiatives or to be a director of pharmacy or president of ASHP. I did, however, set out to do something I was passionate about. I wanted to make an impact.

Conclusion

When I started my remarks today, I talked about Alice in Wonderland and the idea that if you don't have a destination, you'll certainly wind up *somewhere* but maybe not where you'd *like* to be.

Well, I can assure you that as a profession, we know who we are and where we are going! We are the members of the healthcare team who need to be part of every decision regarding medication use.

And as an organization, ASHP also knows what it is and where it is going, leading the way on PPMI; provider status; our vision, mission, and strategic plan; and our focus on the entire continuum of care (including ambulatory practice).

We are moving hand-in-hand with you toward providing the best care for our patients and ensuring that pharmacists are recognized as the constant.

So, let me end with one more equation to solve, with pharmacists as the constant:

Pharmacists
 + residents
 + students
 + technicians
 + the healthcare team
 + patients

 best patient care

It's time to take our place as the constant in patient care!

Let me know what you are doing to improve patient care in your organization. Be sure to email me at prez@ashp.org.

Thank you for all that you do to keep pharmacists as the constant in the patient care equation!

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Professional Policies Approved by the 2014 ASHP House of Delegates

LAS VEGAS, NV

JUNE 3, 2014

Am J Health-Syst Pharm. 2014; 71:e17-21

The new professional policies approved by the ASHP House of Delegates at its June 2014 session are listed below. Policies proposed by councils or other ASHP bodies are first considered by the Board of Directors and then acted on by the House of Delegates, which is the ultimate authority for ASHP positions on professional issues.

The background information on these policies appears on the ASHP Web site (www.ashp.org); click on "Practice and Policy" then on "House of Delegates," and then on "Board of Directors Reports on Councils" (<http://www.ashp.org/DocLibrary/Policy/HOD/CouncilReports.aspx>).

The complete proceedings of the House of Delegates will be provided to delegates and will be posted on the ASHP Web site; a printed copy can be requested from the ASHP Office of Policy, Planning and Communications.

1401

Standardization of Oral Liquid Medication Concentrations

Source: Council on Pharmacy Practice

To advocate for the development of nationally standardized drug concentrations for oral liquid medications; further,

To encourage all health care providers and organizations to standardize concentrations of oral liquid medications; further,

To promote effective instruction of patients and caregivers on how to properly measure and administer oral liquid medications.

1402

Safe Use of Radiopharmaceuticals

Source: Council on Pharmacy Practice

To affirm that radiopharmaceuticals require the same standards for safe medication use as other medications, including but not limited to standards for procurement, storage and control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, disposal, and formulary consideration; further,

To advocate that pharmacy departments, in cooperation with departments of nuclear medicine, radiology, and radiation safety, provide oversight of radiopharmaceuticals to assure safe use; further,

To advocate for incorporation of information on radiopharmaceuticals into college of pharmacy curricula and increased pharmacy continuing education on radiopharmaceuticals.

1403

Pharmacist's Role on Ethics Committees

Source: Council on Pharmacy Practice

To advocate that pharmacists should be included as members of hospital and health-system ethics committees; further,

To encourage pharmacists to actively seek ethics consultations as appropriate; further,

To encourage pharmacists serving on ethics committees to seek advanced training in health care ethics.

1404

Safe Use of Fentanyl Transdermal System Patches

Source: Council on Pharmacy Practice

To advocate for enhanced consumer education and product safety requirements for fentanyl transdermal system patches; further,

To encourage manufacturers of fentanyl transdermal system patches to collaborate with pharmacists and other stakeholders to identify and implement packaging, labeling, and formulation changes that prevent accidental exposure and facilitate safe disposal.

1405

Automatic Stop Orders

Source: Council on Pharmacy Practice

To advocate that the Centers for Medicare & Medicaid Services (1) remove the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other

options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice; further,

To affirm that the requirement for automatic stop orders for all medications is a potential source of medication errors and patient harm; further,

To encourage pharmacists to participate in interprofessional efforts to establish standardized methods to assure appropriate duration of therapy.

This policy supersedes ASHP policy 0904.

1406

Federal and State Regulation of Compounding

Source: Council on Public Policy

To advocate that the applicable compendial standards of the United States Pharmacopeia be included in state and federal laws and regulations that govern compounding by any health professional; further,

To advocate for mandatory state registration of compounding facilities (e.g., pharmacies, physician offices, clinics, ambulatory surgery centers) that provide products for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders; further,

To advocate for mandatory Food and Drug Administration registration and current good manufacturing practices requirements for outsourcing facilities that compound and sell products without patient-specific prescriptions across state lines; further,

To advocate for improved patient safety and care through education of regulatory inspectors, increased frequency and improved effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate that state and federal agencies develop standardized definitions and nomenclature relating to sterile and nonsterile compounding, including but not limited to definitions of compounding, manufacturing, repackaging, and relabeling.

This policy supersedes ASHP policy 1308.

1407

340B Drug Pricing Program Sustainability

Source: Council on Public Policy

To affirm the intent of the federal drug pricing program (the “340B program”) to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; further,

To encourage communication and education concerning expanded

services and access provided by 340B participants to patients in fulfillment of its mission.

This policy supersedes ASHP policy 0506.

1408

State Prescription Drug Monitoring Programs

Source: Council on Public Policy

To advocate for mandatory, uniform prescription drug monitoring programs that collect real-time, relevant, and standard information from all dispensing outpatient entities about controlled substances and monitored prescriptions; further,

To advocate that the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further,

To advocate that such programs be structured as part of electronic health records and exchanges to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment; further,

To advocate for full interstate integration to allow for access by prescribers, pharmacists, and other qualified designees across state lines; further,

To advocate for federal and state funding to establish and administer these programs; further,

To promote research, education, and implementation of best practices in prescription drug monitoring programs.

This policy supersedes ASHP policy 1122.

1409

Approval of Biosimilar Medications

Source: Council on Public Policy

To encourage the development of safe and effective biosimilar medica-

tions in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,

To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,

To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; further,

To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

This policy supersedes ASHP policy 1218.

1410

Access to Oral Contraceptives Through an Intermediate Category of Drug Products

Source: Council on Therapeutics

To advocate that oral contraceptives be provided only under condi-

tions that ensure safe use, including the availability of counseling to ensure appropriate self-screening and product selection; further,

To support expanded access to these products through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications; further,

To advocate that the proposed reclassification of these products be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised and that pharmacists are reimbursed for the clinical services provided.

1411

Expedited Pathways for FDA Drug Approval

Source: Council on Therapeutics

To support the use of expedited pathways for Food and Drug Administration (FDA) approval of new drugs that expand access to innovative therapies while protecting patient safety; further,

To advocate for the development of unique labeling requirements that would be used on an interim basis to identify products approved by these pathways in order to increase awareness of data limitations and guide clinician use of these drugs until additional evidence becomes available; further,

To advocate that the FDA be diligent in enforcing postmarketing commitments for drug products approved via expedited pathways, including utilizing its existing authority to enforce penalties when these requirements are not met; further,

To encourage research to evaluate the impact of expedited pathways on drug product development and patient care, including drug development timelines and costs, overall

health care costs, patient access to care, and the effectiveness and safety of these therapies.

1412

FDA Oversight of Laboratory-Developed Tests

Source: Council on Therapeutics

To advocate that the Food and Drug Administration be granted increased authority to regulate laboratory-developed tests as medical devices, including tests used for pharmacogenetic testing; further,

To support development of a risk-based framework for regulatory oversight of laboratory-developed tests that promotes innovation while providing a mechanism to ensure that test results are reliable, reproducible, and clinically relevant; further,

To encourage expanded availability of commercially marketed pharmacogenetic tests that would be available for use by laboratory and health care professionals to guide drug therapy.

1413

Ensuring Effectiveness, Safety, and Access to Orphan Drug Products

Source: Council on Therapeutics

To encourage continued research on and development of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of these drug products for approved and off-label indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products.

This policy supersedes ASHP policy 0715.

1414

Cultural Competency and Cultural Diversity

Source: Council on Education and Workforce Development

To promote the development of cultural competency of pharmacy educators, practitioners, residents, students, and technicians; further,

To educate providers on the importance of providing culturally congruent care to achieve quality care and patient engagement; further,

To foster awareness of the impact that an ethnically and culturally diverse workforce has on improving health care quality.

This policy supersedes ASHP policies 0314 and 0409.

1415

Credentialing, Privileging, and Competency Assessment

Source: Council on Education and Workforce Development

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

This policy supersedes ASHP policy 0006.

1416

Pharmacy Department Business Partnerships

Source: Council on Pharmacy Management

To recognize that a key objective of pharmacy departments is to provide comprehensive medication

management across the continuum of patient care, and that pharmacy leaders should proactively evaluate potential business partnerships against this objective; further,

To recognize that hospitals and health-system pharmacy leaders must ensure that business partners meet all applicable patient safety and accountability standards; further,

To provide education and tools for pharmacy leaders to aid in the evaluation of and development of business partnerships; further,

To educate health-system administrators on the importance of pharmacy leadership in evaluating and developing pharmacy-related business partnerships; further,

To encourage health-system pharmacy leaders to consider evolving health care financing systems when evaluating and developing business partnerships.

1417

Integration of Pharmacy Services in Multifacility Health Systems

Source: Council on Pharmacy Management

To advocate that pharmacists are responsible for organizational efforts to standardize and integrate pharmacy services throughout the entire pharmacy enterprise in multifacility health systems and integrated delivery networks; further,

To educate health-system administrators about the importance of pharmacy leadership in setting system-wide policy regarding the safe and effective use of medications; further,

To advocate for the regulations and resources needed to support efforts to achieve optimal patient health outcomes in multifacility organizations.

This policy supersedes ASHP policy 1210.

1418

Risk Assessment of Health Information Technology

Source: Council on Pharmacy Management

To urge hospitals and health systems to directly involve departments of pharmacy in performing appropriate risk assessment before new health information technology (HIT) is implemented or existing HIT is upgraded, and as part of the continuous evaluation of current HIT performance; further,

To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,

To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes; further,

To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

1419

Documentation of Patient-Care Services in the Permanent Health Record

Source: Council on Pharmacy Management

To advocate for public and organizational policies that support pharmacist documentation of patient-care services in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of pharmacist patient care on patient outcomes and total cost of care; further,

To advocate that electronic health records be designed with a common documentation space to accommodate all health care team members and support the communication needs of pharmacy.

This policy supersedes ASHP policy 0407.

1420

Manufacturer-Sponsored Patient-Assistance Programs

Source: Council on Pharmacy Management

To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drugs used in inpatient settings; further,

To encourage pharmacists and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

This policy supersedes ASHP policies 0404 and 9703.

1421

ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics

Source: Section of Clinical Specialists and Scientists

To approve the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics.*

*The ASHP statement approved by the House of Delegates is available on the ASHP Web site (www.ashp.org). Under "Practice and Policy," click on "Policy Positions & Guidelines" and then on "New Guidance Documents."

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Governing Documents of the American Society of Health-System Pharmacists

ASHP CHARTER

First. The undersigned, whose names and post office addresses are set forth at the end of this document, each being at least 18 years of age, do hereby form a corporation under the general laws of the state of Maryland.

Second. The name of the corporation is American Society of Health-System Pharmacists, Inc. (ASHP).

Third. The purposes for which ASHP is formed are as follows:

1. To advance public health by promoting the professional interests of pharmacists practicing in hospitals and other organized health care settings through:
 - a. Fostering pharmaceutical services aimed at drug-use control and rational drug therapy.
 - b. Developing professional standards for pharmaceutical services.
 - c. Fostering an adequate supply of well-trained, competent pharmacists and associated personnel.
 - d. Developing and conducting programs for maintaining and improving the competence of pharmacists and associated personnel.
 - e. Disseminating information about pharmaceutical services and rational drug use.
 - f. Improving communication among pharmacists, other members of the health care industry, and the public.
 - g. Promoting research in the health and pharmaceutical sciences and in pharmaceutical services.
 - h. Promoting the economic welfare of pharmacists and associated personnel.
2. To foster rational drug use in society such as through advocating appropriate public policies toward that end.
3. To pursue any other lawful activity that may be authorized by ASHP's Board of Directors.

Fourth. The post office address of the principal office of ASHP in Maryland is 7272 Wisconsin Avenue, Bethesda (Montgomery County), Maryland 20814. The name and post office address of the resident agent of ASHP in Maryland is C.T. Corporation Systems, Inc., 32 South Street, Baltimore, Maryland 21202. The resident agent of ASHP is a Maryland corporation.

Fifth. ASHP shall be a not-for-profit corporation and shall not be authorized to issue capital stock. No part of the net earnings of ASHP, current or accumulated, shall inure to the benefit of any private individual, nor shall ASHP be operated for the primary purpose of carrying on a trade or business for profit. ASHP intends to avail itself of any and all tax benefits or exemptions to which it may be entitled under Section 501 of the Internal Revenue Code of 1954, and it shall not operate or engage in any activity nor shall it possess or exercise any power that would substantially risk the loss of such benefits under that Code.

Sixth. The number of Directors of ASHP shall be 12, which number may be increased or decreased only by amendment to this Charter. The Board of Directors shall consist of six Directors who shall be elected at large by a majority of votes cast by active members; the Chair of the House of Delegates; and the officers of ASHP, to wit, the President, the President-elect, the Immediate Past President, the Treasurer, and the Secretary. The Directors, who shall act until the first annual meeting or until their successors are duly chosen and qualified, as set forth in the Bylaws, are Roger W. Anderson, John A. Gans, Thomas J. Garrison, Clifford E. Hynniman, Marianne F. Ivey, Herman L. Lazarus, Harland E. Lee, Arthur G. Lipman, Joseph A. Oddis, Judith A. Patrick, Paul G. Pierpaoli, and Marilyn L. Slotfeldt. The Directors of ASHP shall manage its business affairs. All Directors shall be active members of ASHP.

Seventh. The following provisions are hereby adopted for the purposes of defining, limiting, and regulating the internal affairs of ASHP:

1. The membership of ASHP shall consist of active members, associate members, honorary members, and such other categories as may be established in the Bylaws. Active members shall be licensed pharmacists who support the purposes of ASHP as stated in the Article Third of this Charter; the other requirements for active membership shall be stated in the Bylaws. Only active members may (a) vote as individual members on amendment to this Charter as provided in Charter item 11, (b) serve as state delegates to the House of Delegates, (c) elect the Directors of ASHP, and (d) serve as a Director of ASHP. The definition, rights, powers, and obligations of each class of members not set forth herein shall be established and limited by the Bylaws.
2. ASHP shall have a House of Delegates that shall meet yearly to review, consider, and ultimately approve or disapprove the professional policies recommended to it by its Directors and to review the affairs of ASHP; voting delegates in the House of Delegates shall consist of the following classes: state delegates, who shall be active members and shall be deemed to represent the aliquot portion of the active membership of ASHP, plus Directors, plus eligible Past Presidents of ASHP, plus fraternal delegates, plus the chair of each Section and Forum created by the Board pursuant to Article 6.1.6 of the bylaws.
 - 2.1. The House of Delegates shall have at least two state delegates from each state.
 - 2.2. The House of Delegates shall elect a Chair to preside at all of its meetings.
3. ASHP may establish and shall try to promote and strengthen ongoing cooperative relationships with other domestic and international organizations when such relationships further the purposes of ASHP.

4. ASHP shall try to formally recognize, promote, and strengthen relationships with groups of pharmacists in the various states and possessions of the United States when such groups promote and foster the purposes of ASHP.

Eighth. Upon termination, dissolution, or winding up of ASHP, any assets that remain after payment or provision for payment of all of its liabilities, debts, and obligations shall be distributed by the Board of Directors only to one or more organized charitable, educational, scientific, or philanthropic organizations duly qualified as exempt under Section 501(c)(3) of the Internal Revenue Code of 1954 (or under such successor provision of the Internal Revenue Code as may be in effect at the time of termination, dissolution, or winding up of ASHP). Under no circumstances shall any assets be distributed to any member of ASHP.

Ninth. The private property of the members, officers, Directors, and employees of ASHP shall not be subject to payment of any debts or obligations of ASHP.

Tenth. The Bylaws shall delineate the authority of the Board of Directors and govern the internal affairs of ASHP. The Bylaws may be amended as provided therein.

Eleventh. Any proposed amendment to this Charter must first be submitted to the Board of Directors. Upon review, the Board shall submit the proposed amendment to the House of Delegates. Upon approval of a majority of the voting delegates of the House of Delegates then present and voting, it shall be submitted to the entire active membership for vote by mail ballot in the same manner as in the election of officers as provided in the Bylaws and shall be sent out as part of the ballot for officers.

Twelfth. The duration of ASHP shall be perpetual.

BYLAWS

Article 1. Name and Seal

- 1.1. The name of the corporation shall be the “American Society of Health-System Pharmacists, Inc.,” which will be referred to as ASHP.
 - 1.1.1. The official corporate seal of ASHP, which shall be used as needed to authenticate documents of ASHP, shall consist of the word “Seal” as authorized by Section 1-304 of the Corporations and Associations Article of the Code of Maryland.
- 1.2. ASHP may adopt and use such trade names, trademarks, service names, and service marks as, in its judgment, are necessary or appropriate to identify or designate its products and services and to carry on its business.
 - 1.2.1. No member, chapter, organizational component, or third party may use any name or mark of the ASHP unless such use conforms to the standards established by the Board of Directors and unless the Board has specifically approved such use in writing.

Article 2. Offices and Agent

- 2.1. ASHP shall continuously maintain, in the state of Maryland, a registered office at such place as may be established by the Board of Directors. The Board of Directors may establish ASHP’s principal place of business and other offices and places of business either inside or outside the state.
- 2.2. ASHP shall continuously maintain a registered agent within the state of Maryland, which shall be designated, from time to time, by the Board of Directors.

Article 3. Membership

- 3.1. The classifications of membership in ASHP are as follows:
 - 3.1.1. *Active Members*: Pharmacists licensed by any state, district, or territory of the United States who have paid dues as established by ASHP; practice in the jurisdictions of the United States, the District of Columbia, or Puerto Rico; and who support the purposes of ASHP as stated in the Article Third of the ASHP Charter.
 - 3.1.1.1. Only active members may vote on amendment to the Charter, serve as state delegates, and elect or serve as a Director of ASHP.
 - 3.1.2. *Associate Members*: Persons who have paid the dues as established by ASHP and who, by virtue of vocation, training, education, and interest, wish to further the purposes of ASHP. Associate members shall consist of the following categories:
 - 3.1.2.1. *Supporting*: Individuals, other than those who qualify as active members, who by working in the health services, teaching prospective pharmacists, or otherwise contributing to pharmacy services provided in organized health care systems, make themselves eligible for membership.

Article 4. Officers

- 4.1.** The officers of ASHP shall be the President, the President-elect, the Immediate Past President, the Treasurer, and the Secretary, all of whom shall be active members of ASHP. The Secretary shall also serve as Executive Vice President of ASHP.
- 4.1.1.** The President-elect shall be elected annually for a term of one year and shall succeed successively to the office of President and then to the office of Immediate Past President, serving for one year in each office.
- 4.1.2.** The Executive Vice President shall be chosen by the Board of Directors.
- 4.1.3.** The candidates for Treasurer shall be nominated by the Board of Directors and elected by the active members for a term of office of three years. No person shall serve more than two successive terms as Treasurer.
- 4.1.4.** Each officer shall be installed at the yearly meeting of the House of Delegates.
- 4.1.5.** The President, President-elect, Immediate Past President, and Treasurer are not charged with executive or administrative responsibility for the management or conduct of the internal affairs of ASHP.
- 4.2.** The President shall serve as the principal elected official of ASHP; serve as Chair of the Board of Directors; serve as Chair of the Committee on Resolutions; at the House of Delegates, communicate to the delegates on the actions of the Board of Directors and on important new activities that affect and further the purposes of ASHP; and communicate with members of ASHP, affiliated chapters, and the public on the activities and policies of ASHP.
- 4.2.1.** With the approval of the Board of Directors, the President shall annually appoint Chairs and members of the councils, commissions, committees, and other appropriate components set forth in Article 6 of these Bylaws and any ad hoc committee or groups that the Board of Directors establishes.
- 4.2.2.** The President shall be an ex-officio member of all councils and committees of the Board of Directors and all ad hoc committees.
- 4.2.3.** The President shall report to the Board of Directors on official activities and shall advise the Board of Directors on such matters as may further the purposes of ASHP.
- 4.3.** The President-elect shall perform the duties of the President in the President's absence; succeed to that office upon the death, resignation, or inability of the President to perform the duties of that office; serve as Vice Chair of the Board of Directors; and assist in communicating the policies and activities of ASHP to its affiliated chapters, members, and the public.
- 4.3.1.** The President-elect shall communicate to the House of Delegates and the membership on those issues and activities that may affect and further the purposes of ASHP.
- 4.3.2.** The President-elect shall report to the Board of Directors on official activities and shall advise the Board of Directors on such matters as may further the purposes of ASHP.
- 4.3.3.** A President-elect who succeeds to the office of President as provided in Section 4.3 shall serve out both the unfinished term to which he or she has succeeded and the term to which he or she would have succeeded in due course.

- 4.3.4.** The President-elect shall be nominated by the Committee on Nominations of the House of Delegates and elected by the active membership of ASHP as set forth in Article 7 of these Bylaws.
- 4.4.** The Immediate Past President shall perform the duties of the President in the temporary absence of both the President and President-elect, serve as Vice Chair of the House of Delegates, and serve in such other capacity as may be designated by the Board of Directors.
- 4.4.1.** The Immediate Past President shall report to the Board of Directors on his or her activities and shall advise the Board of Directors on such matters as may further the purposes of ASHP.
- 4.5.** The Treasurer shall serve as the Chair of the Committee on Finance, as specified in Section 5.2; be responsible for overseeing conservation and prudent investment of the assets and funds of ASHP; assure expenditure of funds is in accord with the programs, priorities, and budget established by the Board of Directors; and regularly inform the Board of Directors, members, and House of Delegates on the financial strength and needs of ASHP.
- 4.5.1.** No monies shall be disbursed except upon signature of the Treasurer and the Executive Vice President. The Treasurer shall periodically review and approve internal controls designed to assure proper control of funds and disbursements and make sure that current and projected income and expenses meet the budget of ASHP.
- 4.5.2.** The Board of Directors may, at all times, inspect and verify the books and accounts of ASHP.
- 4.5.3.** The Treasurer shall review and report upon the long-term financial projections and plans of ASHP.
- 4.6.** The Executive Vice President shall serve as the chief executive officer and as Secretary of ASHP.
- 4.6.1.** The Executive Vice President shall be responsible for administration of ASHP; direction of all operations, programs, and activities of ASHP; and hiring, firing, and the compensation and benefits of staff, subject to establishment of general salary and benefit policies by the Board of Directors. The Executive Vice President shall, at all times, carry out the policy aims and programs as generally determined by the Board of Directors.
- 4.6.2.** As Secretary, the Executive Vice President shall keep and maintain an accurate record of the meetings of the Board of Directors, the House of Delegates, and such other activities of ASHP as the Board of Directors may direct. The Executive Vice President shall give all notices required by law. The Executive Vice President shall have authority to affix the corporate seal to any document requiring it and attest thereto by his or her signature.
- 4.6.3.** The Executive Vice President may appoint an Assistant Secretary to attest to documents.
- 4.6.4.** The Executive Vice President shall, by virtue of the office, be a nonvoting member of all councils, commissions, and committees of the Board of Directors; committees of the House of Delegates; and any other committee or component group established by the Board of Directors.

- 4.6.5.** The Executive Vice President shall be chosen by and serve at the pleasure of the Board of Directors. The Board of Directors may, on behalf of ASHP, enter into a contract with the Executive Vice President with such terms and for such fixed period as the Board of Directors deems reasonable and in the best interests of ASHP. Failure of a person to continue in the office of Executive Vice President will not affect contract rights, except as the terms of that contract may so provide.
- 4.7.** The manner of filling vacancies of any office shall be as follows:
- 4.7.1.** The provision of Sections 4.3 and 4.3.3 shall apply.
- 4.7.2.** If both the President and the President-elect shall become permanently unable to perform the duties of their offices, the Board of Directors shall appoint, from the Board of Directors, a President Pro Tempore to serve for the remaining portion of the unexpired term. At the next yearly meeting of the House of Delegates, the Committee on Nominations shall present nominations for the offices of President and President-elect, and an election shall be conducted in accordance with the provisions of Article 7 of these Bylaws.
- 4.7.3.** If the Executive Vice President or the Treasurer becomes unable to perform the duties of his or her office, the Board of Directors is empowered to fill that vacancy.
- 4.7.4.** If the Immediate Past President is permanently unable to perform the duties of that office, the Board of Directors shall appoint a Director of ASHP to perform the duties of that office.
- 4.8.** The following miscellaneous provisions shall apply:
- 4.8.1.** To the extent not prohibited by these Bylaws, the officers may also exercise the powers that, by statute or otherwise, are customarily exercised by officers holding such offices or that may be established by the Board of Directors. However, only the Executive Vice President or an individual appointed by the Executive Vice President may execute, on behalf of ASHP, contracts, leases, debt obligations, and all other forms of agreement. An officer of ASHP may sign an instrument that must be executed by the Executive Vice President and that other officer. The Board of Directors may authorize any two officers to jointly execute a specific document or instrument.
- 4.8.2.** Except to the extent specifically authorized by the Board of Directors, no officer shall be entitled to any compensation for services. In accordance with policies established by the Board of Directors, officers may be reimbursed for reasonable expenses incurred in discharging the functions of the office.

Article 5. Board of Directors

- 5.1.** The Board of Directors shall consist of 12 persons: the officers of ASHP, the Chair of the House of Delegates, and six Directors at large.
- 5.1.1.** The term of office for a Director, who also serves as an officer or as Chair of the House of Delegates, shall be the term for that office, and the manner of election and filling vacancies in such offices shall be as specified in the Bylaws dealing with those offices.
- 5.1.2.** Directors at large shall be nominated by the Committee on Nominations of the House of Delegates and elected as set forth in Section 7.4.

- 5.1.3.** Elected Directors shall serve for one term of three years beginning with installation at the yearly meeting of the House of Delegates following their election. Elected Directors may not serve more than one term as a member at large.
- 5.1.4.** If the office of an elected member of the Board of Directors shall become vacant between yearly meetings of ASHP because of resignation, death, or otherwise, the Board of Directors may fill the vacancy. At the next yearly meeting of the House of Delegates, the Committee on Nominations shall present candidates for election to serve for the remaining portion of the unexpired term.
- 5.2.** The Committee on Finance shall report to the Board and shall consist of the President, the President-elect, the Immediate Past President, the Executive Vice President, and the Treasurer; the Treasurer shall be its Chair. The Committee on Finance shall prepare a budget for the forthcoming year and submit it to the Board of Directors for approval; review, assess, and monitor operations of ASHP to assure that budget objectives are met or that appropriate changes thereto are made; review and assess performance of investments and assets of ASHP; review all investment policies and financial policies of ASHP; oversee the responsibilities of the Treasurer set forth in Section 4.5; and oversee the financial operations of ASHP.
- 5.3.** The Board of Directors shall meet annually, in conjunction with the yearly meeting of the House of Delegates, and at such other times as the Board may determine. A special meeting shall be held upon written application of any three Directors or of the President.
- 5.3.1.** The Secretary shall establish the time and place of scheduled and special meetings and shall give the Directors reasonable advance notice thereof by mail or other mode of transmittal.
- 5.3.2.** No Director shall be entitled to any compensation for services. Pursuant to policies adopted by the Board, Directors may be reimbursed for reasonable expenses incurred in attending meetings of the Board of Directors and in discharging functions at the direction of the Board.
- 5.4.** The Board of Directors shall manage the affairs of ASHP, establish policies within the limits of the Bylaws, actively pursue the purposes of ASHP, and have discretion in the control, management, investment, and disbursement of its funds. The Board of Directors, through its Committee on Finance, shall develop and approve an annual budget, establish financial goals for ASHP, and oversee the financial operations of ASHP. The Board of Directors shall establish and review long-term objectives of ASHP and establish the priority of all programs and activities. The Board may establish whatever rules and regulations for the conduct of its business it deems advisable and may appoint whatever agents it considers necessary to carry out its powers.
- 5.4.1.** The Board of Directors may establish committees and task forces and designate representatives to other organizations.
- 5.4.2.** The Board of Directors may make contributions of ASHP assets to other organizations for research and education activities of benefit to pharmacists practicing in organized health care systems. The Board may also accept

grants, contributions, gifts, bequests, or devices to further the purposes of ASHP.

- 5.4.3.** The Board of Directors shall create, review, and modify the professional policies of ASHP and submit those policies to the House of Delegates for such action as the House of Delegates may choose to take under Article 7. The Board of Directors shall approve or disapprove all recommendations of the components of ASHP set forth in Article 6 and any committee or group created by, or which reports to, the Board of Directors. Further, the Board of Directors shall report annually to the House of Delegates how it has handled such recommendations so that the House of Delegates can take final action as required or appropriate under Article 7.
- 5.4.4.** The Board of Directors shall approve all nominations to all committees, councils, and commissions, except as membership is specified in Article 6.
- 5.4.5.** The Board of Directors may establish and modify administrative policies, not inconsistent with these Bylaws, for the conduct of its business and for the conduct of the business of ASHP and its components, except for the House of Delegates, which may establish its own regulations.
- 5.4.6.** The Board of Directors and the officers shall tender reports at such times and in such manner as are required by law.

Article 6. Components

- 6.1.** The Board of Directors may establish councils, commissions, committees, joint committees, sections, forums and other appropriate component groups of ASHP, and such components shall operate to further the purposes of ASHP. The Board of Directors may modify, change, or eliminate components based on the needs of ASHP and its membership.
 - 6.1.1.** The Commission on Credentialing shall consist of a Chair and as many ASHP members and individuals from other disciplines as may be deemed necessary. The Commission shall formulate and recommend standards for accreditation of pharmacy personnel training programs, administer programs for accreditation of pharmacy personnel training programs, and perform such other functions as related to the development and recognition of pharmacy personnel and areas of pharmacy practice as may be assigned by the Board of Directors.
 - 6.1.1.1.** One or more members shall be appointed from the public sector.
 - 6.1.1.2.** The term of appointment shall not exceed three years. Commission members may be appointed to subsequent terms.
 - 6.1.2.** ASHP shall have councils that report to the Board of Directors and recommend professional policy positions within their areas of concern. Councils may also review ongoing activities of ASHP and recommend new programs within their areas of interest. The councils shall consist of a Chair and those members appointed by the President, with the approval of the Board of Directors. The President shall appoint a Director to each council who shall attend all meetings of the council as an observer and present council recommendations to the Board of Directors.

- 6.1.3.** The President, with the approval of the Board of Directors, may establish and appoint joint committees with other organizations. Joint committees shall meet to discuss and recommend to each parent organization solutions to problems of mutual interest.
- 6.1.4.** Sections and Forums are components of ASHP established by the Board of Directors. The Board of Directors may also establish rules and criteria (including financial criteria) to join and maintain enrollment in a Section or Forum for the administration of the affairs of the Section or Forum. ASHP members who meet the criteria may be members of the Section or Forum.
- 6.1.4.1.** Sections and Forums shall be operated to further the purposes of ASHP by fostering the development, enhancement, and recognition of pharmacy practice as represented by the Section or Forum.
- 6.2.** The components of ASHP established pursuant to this Article 6 shall have only those powers granted herein. The Board of Directors may establish administrative guidelines for the scope and operation of these components.
- 6.2.1.** In no case shall a component independently contact other organizations, seek or attempt to secure funds from outside ASHP, or commit any funds of ASHP without prior authorization from the ASHP Board of Directors.

Article 7. House of Delegates

- 7.1.** The House of Delegates shall consist of 163 voting state delegates, who shall represent a proportionate number of active members in each state; plus all Directors of ASHP; plus Past Presidents (if active members) after completing the term of office of Immediate Past President; plus five (voting) fraternal delegates; plus the (voting) chair of each Section and Forum. Each delegate shall have one vote, and no delegate may have more than one vote by virtue of any dual capacity in the House of Delegates.
- 7.1.1.** Delegates shall be chosen as follows:
- 7.1.1.1.** As soon as convenient after July 1 in every fourth year beginning with the year 1983, the Board of Directors shall apportion 163 delegates among the states in proportion, as nearly as can be, to the total of active ASHP members in each state as recorded. Each state shall have at least two delegates. For the purpose of computing the reapportionment, the Board of Directors shall use the total number of active members during the immediately preceding year. This apportionment shall prevail until the next quadrennial apportionment, whether the ASHP membership from a particular state increases or decreases.
- 7.1.1.2.** Affiliated state chapters shall administer the election of voting state delegates for the House of Delegates. The chapter shall conduct an election to elect voting state delegates from among the active members of ASHP within that state; only active members shall vote in that election. Each state shall certify and transmit, to the Executive Vice President of ASHP, the names and addresses of the elected delegates, and such delegates shall be deemed thereupon to be duly qualified. Delegates shall continue in office until the next election and

certification. Any issue or question relating to qualification or eligibility of any delegate or alternate shall be referred to and resolved by the ASHP Board of Directors.

- 7.1.1.3.** In those states where no affiliated state chapter exists, the President of ASHP shall appoint, from among the active members of ASHP in the state, a committee of three, designating a Chair and a Secretary, for the purpose of conducting an election for delegates and alternates from active members in the state.
- 7.1.1.4.** The United States Army, Navy, Air Force, Public Health Service, and Veterans Administration shall each be entitled to designate one voting fraternal delegate.
- 7.1.1.5.** Alternates for voting state delegates shall be chosen in the same manner as that designated for choosing voting state delegates. Alternates shall not be entitled to any of the rights or privileges for delegates until, pursuant to the Rules of Procedure of the House of Delegates, the alternate replaces a voting state delegate.
- 7.1.2.** The House of Delegates shall elect a Chair who shall be installed immediately upon election and serve a three-year term.
 - 7.1.2.1.** The Chair shall be elected by written or electronic ballot of a majority vote of the delegates present and voting in the House of Delegates. The Chair may not serve for more than one three-year term.
 - 7.1.2.2.** The Chair shall serve as liaison between the submitter of resolutions for consideration by the House of Delegates and the Committee on Resolutions.
- 7.1.3.** The Immediate Past President shall serve as Vice Chair of the House of Delegates.
- 7.1.4.** The Executive Vice President of ASHP shall serve as Secretary of the House of Delegates.
- 7.1.5.** Members of ASHP shall have no right to vote in the House of Delegates except by virtue of status hereunder.
- 7.2.** A yearly session (consisting of at least two meetings) of the ASHP House of Delegates shall be held at such time and place as may be established; the House of Delegates shall conduct such business as may come before it. Special online sessions of the House of Delegates may be called by the Board of Directors or by the Chair of the House of Delegates, provided that such request contains the specific topic or topics to be considered at that meeting.
 - 7.2.1.** The Secretary shall notify each member selected as a delegate to the House of Delegates at least 30 days in advance of its yearly session and any special session.
 - 7.2.2.** ASHP shall use reasonable means to notify the membership of yearly and special sessions and to encourage their participation therein, to the extent authorized by these Bylaws.
 - 7.2.3.** A majority of voting members of the House of Delegates who have enrolled for that session shall constitute a quorum at any session or meeting duly convened. In the absence of a quorum, the Chair may recess any session or meeting until such time as a quorum is present.

- 7.3.** The House of Delegates shall conduct its business at its yearly or special online session.
- 7.3.1.** The House of Delegates shall review and oversee the professional affairs of ASHP to further its purposes.
- 7.3.1.1.** ASHP professional policy, as approved by the Board of Directors, shall be submitted to the House of Delegates for its review, consideration, modification, approval, or disapproval. In the event the House of Delegates fails to approve a matter as submitted to it, the House shall note the reason in its proceedings and return the matter to the Board of Directors for review, modification, or other action. The Board of Directors shall consider, during its interim meeting between meetings of a House of Delegates session, actions of the House of Delegates that resulted in amendment or modification of an issue presented in the first House meeting. The Board shall report its recommendations pertaining to these amendments or modifications during its report in the second meeting of the House session. If, after Board reconsideration, the House disagrees with the Board recommendation pertaining to disposal of an issue, the House may, by two-thirds vote of certified and registered delegates, reconsider the issue for approval. If, on reconsideration, the House fails to approve the matter as previously amended or modified, the House shall note the reason in its proceedings and return the matter to the Board of Directors for review, modification, or other action. The Board of Directors shall then duly report its action thereon at the next session of the House of Delegates.
- 7.3.1.2.** Individual delegates may make recommendations to the Board of Directors on such matters as each delegate deems appropriate.
- 7.3.1.3.** As to any resolution or item of business presented to the House, the Board shall normally certify that it has duly considered the matter. However, if the House of Delegates should debate a matter that the Board of Directors has not so considered, action taken by the House will be by vote to refer the proposed matter to the Board of Directors for review before the House of Delegates takes action on that matter or to reject the issue. The Board shall report on that matter for consideration by the House at the next session of the House of Delegates. If the Board of Directors rules that bona fide, extraordinary circumstances require immediate action and if a majority of the delegates present and voting concur, the House of Delegates may exercise extraordinary authority and amend, modify, or substitute any matter placed before it.
- 7.3.2.** By majority vote, the House of Delegates may establish its Rules of Procedure, to be effective at the next meeting of the House.
- 7.3.3.** All officers and Directors of ASHP shall be installed before the House of Delegates at the commencement of their individual terms of office.
- 7.3.4.** The House of Delegates shall, except as is otherwise specifically provided for in these Bylaws, have no authority over the financial affairs of ASHP.

- 7.3.5.** The Chair of the House of Delegates shall preside at all sessions and meetings of the House of Delegates, shall be a member of the Board of Directors, and shall represent the House of Delegates at all Board meetings.
- 7.4.** Election of Directors of ASHP shall be conducted by, or under the auspices of, the Committee on Nominations of the House of Delegates.
- 7.4.1.** The Treasurer shall be elected by written or electronic ballot of a majority vote of the active membership in the same manner as members at large as provided in Section 7.4.3.2 every third year before the term of that office begins. Only nominations for the office of Treasurer from the Board of Directors shall be accepted.
- 7.4.2.** The Chair of the House of Delegates shall be elected by written or electronic ballot of the House of Delegates as provided in Section 7.1.2.
- 7.4.3.** The Chair shall appoint a Committee on Nominations consisting of seven active members who shall have been delegates to the House of Delegates within the last five years at the time of their appointment to serve as a Committee of the House. The Committee shall solicit names of possible candidates for office using such means as it determines to be appropriate.
- 7.4.3.1.** The Committee shall submit to the House of Delegates one or more reports nominating two candidates for the office of President-elect, two candidates for each Director to be elected, and two candidates each for Chair of the House of Delegates. The reports of the Committee shall not be subject to amendment and shall be the exclusive source of nominations for these offices.
- 7.4.3.2.** The names of the candidates for President-elect, Treasurer, and Directors of ASHP shall be submitted by mail or electronic transmission to every active member of ASHP within 60 days after nomination. The active member shall indicate on the ballot a choice of candidates for the offices to be filled and return the same by mail or electronic transmission within 30 days of the date on the ballot.
- 7.4.3.3.** The ballots, postmarked or electronically transmitted within 30 days of the date printed on the ballot, will be submitted to the Board of Canvassers who shall oversee counting of the ballots. The Board of Canvassers shall certify the results of the election to the Executive Vice President. The Executive Vice President shall notify all candidates of the results of the election, and the results of the election shall also be disseminated to the membership.
- 7.4.3.4.** The Board of Directors shall fill all vacancies in the list of candidates that may occur by death or resignation after the adjournment of the annual meeting of ASHP and before the issuance of mail ballots.
- 7.5.** The Committee on Resolutions shall be composed of the Board of Directors and chaired by the President of the Society. The Committee shall review all resolutions. Once duly considered, the Committee shall submit them to the House of Delegates.

Article 8. Affiliated State Chapters

- 8.1.** ASHP shall recognize groups of pharmacists practicing in organized health care systems within the states when such groups promote the purposes of ASHP.

- 8.1.1. Only one group in each state (hereafter, affiliated state chapter) shall be affiliated with ASHP.
 - 8.1.2. ASHP shall establish standards and criteria that a state group must meet to be affiliated with ASHP.
 - 8.2. ASHP shall promote and strengthen affiliations with affiliated state chapters in order to support and fulfill the mission of ASHP and its affiliates.
 - 8.2.1. Affiliated state chapters shall promote the standards and policies of ASHP within the state.
 - 8.2.2. Affiliated state chapters may use the official Society logo and note its affiliation with ASHP under such terms and conditions as may be established by the Board of Directors.
 - 8.2.3. Within the limits of its resources, ASHP shall endeavor to provide services, benefits, and programs to assist affiliated state chapters in furthering the purposes of ASHP and in furthering the organizational strength of affiliated state chapters.
 - 8.2.4. Affiliated state chapters shall administer the election of voting state delegates to the House of Delegates.
 - 8.2.5. Affiliated state chapter involvement is critical to ASHP and should advance the best interests of the membership at the national and state levels, encourage and facilitate two-way information exchange and support between ASHP and the affiliate, and provide benefits to ASHP and the affiliate.
 - 8.3. Affiliation shall not limit the rights of ASHP or the affiliated state chapter.
 - 8.3.1. Affiliated state chapters may not adopt, publicize, promote, or otherwise convey any policy or principle in the name of the American Society of Health-System Pharmacists that has not been officially adopted by ASHP.
 - 8.3.2. Acts of affiliated state chapters shall in no way commit or bind ASHP.
 - 8.3.3. Dues in affiliated state chapters may be set at the discretion of the chapter. Dues in ASHP shall be established pursuant to these Bylaws.

Article 9. International Cooperation

- 9.1. ASHP shall endeavor to promote and foster relationships with pharmacy organizations from other countries and with international pharmacy and health organizations when such furthers the purposes of ASHP.

Article 10. Miscellaneous

- 10.1. The following terms used in these Bylaws shall mean the following:
 - 10.1.1. “Notice” shall be delivered personally, electronically, or by mail to the primary address of the person to receive such notice. If such notice is given by mail, it shall be deemed delivered when deposited in the United States mail properly addressed and with postage paid thereon.
 - 10.1.2. “State” shall mean the 50 jurisdictions of the United States customarily called states, plus the District of Columbia and Puerto Rico.
- 10.2. At the direction of the Board of Directors, any officer or employee of ASHP shall furnish, at the expense of ASHP, a fidelity bond in such a sum as the Board shall provide.

- 10.3.** ASHP may indemnify each Director, officer, former Director, and former officer of ASHP against expenses (including attorneys' fees), judgments, fines, penalties, and settlements actually and necessarily incurred by that person in connection with or arising out of any proceeding in which that person may be involved as a party or otherwise by reason of being or having been such Director or officer.
- 10.3.1.** No indemnification shall be made until the Board of Directors or ASHP shall have determined that indemnification is proper.
- 10.3.2.** The procedure and standard for indemnification shall be governed by the applicable sections of the Corporations and Associations Article and the Annotated Code of Maryland.
- 10.4.** If any provision of these Bylaws should, for any reason, be held to be invalid, the validity of any other provision is not thereby affected.
- 10.5.** Whenever the Board of Directors is given authority with respect to any matter, that authority shall include the ability to modify, change, stop, or eliminate that matter at any time.
- 10.6.** The business of the House of Delegates shall be conducted in accord with such Rules of Procedure as the House of Delegates may establish and, to the extent not covered therein, by the latest edition of Robert's Rules of Order. In no case shall any rule of the House conflict with the Charter or these Bylaws.
- 10.7.** The fiscal year of ASHP shall be a 12-month period beginning on June 1 and ending on May 31.
- 10.8.** The *American Journal of Health-System Pharmacy* shall be the official publication of ASHP. The proceedings of the House of Delegates and the Board of Directors and other official business of ASHP shall be published in the *American Journal of Health-System Pharmacy*.
- 10.9.** ASHP will support a research and education foundation to further development of the profession and as a means to meet the purposes of ASHP; the research and education foundation will, at all times, be a separate and independent entity.

Article 11. Amendment

- 11.1.** Any proposed amendment to these Bylaws must first be submitted to the Board of Directors. Upon review, the Board shall submit the proposed amendment to the House of Delegates. Upon approval of a majority of the voting delegates of the House of Delegates then present and voting, the amendment shall become effective.

The ASHP Charter and Bylaws were approved by the ASHP House of Delegates on June 6, 1984, and by active members of the Society in the 1984 mail ballot annual election. These documents, as subsequently amended, replace the Society's former Articles of Incorporation, Constitution, and Bylaws, effective January 1, 1985. The Regulations for the ASHP House of Delegates were not a part of the 1982–84 governing documents modernization project. These Bylaws and the Rules of Procedure for the House of Delegates were further revised by the ASHP Board of Directors and approved by the ASHP House of Delegates on June 3, 2014; these versions supersede previous versions. The ASHP Charter was not amended in that revision.

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ASHP Rules of Procedure for the House of Delegates

Article 1. Summary and Authority

- 1.1. *Summary:* These Rules of Procedure establish basic rules under which the ASHP House of Delegates operates and conducts its business. These Rules of Procedure are subject to the ASHP Charter and Bylaws but supersede any contrary or inconsistent rule in *Robert's Rules of Order*.
- 1.2. *Authority:* ASHP Bylaws, Section 7.3.2.

Article 2. Rules of Order

- 2.1. The latest edition of *Robert's Rules of Order* shall govern proceedings of the House of Delegates when not inconsistent or in conflict with these ASHP rules; in such cases, these ASHP rules will govern.
 - 2.1.1. In order of precedence, the ASHP Charter and then the ASHP Bylaws, at all times, supersede these ASHP rules and *Robert's Rules of Order*.
 - 2.1.2. The House should be guided by formal interpretation of the governing documents as announced by its Chair and by precedent.

Article 3. Seating of Delegates

- 3.1. Delegates and alternates duly certified and qualified under Section 7.1 of the Bylaws shall be enrolled by the Secretary in advance of a yearly or special session. After the first meeting of a yearly or special session has been called to order, the Secretary shall call the roll of enrolled delegates; those answering the roll shall be recognized as delegates.
 - 3.1.1. Any delegate who, at the first meeting of a House of Delegates session, is recognized and enrolled as a delegate of the House shall remain a delegate of the House until such time as replaced pursuant to this rule.
 - 3.1.2. The place of a recognized and enrolled delegate will not be taken by any other person, except that at the commencement of each meeting the House may, by majority vote, recognize and enroll an alternate delegate (in order of precedence, if designated by the state) if presented, who shall then remain a delegate (in place of the replaced delegate).
 - 3.1.3. In the event neither a delegate nor alternate from a state appears at the commencement of a session of the House, the Secretary shall enroll and the Chair shall recognize the first certified delegate or alternate appearing before the House as the enrolled and recognized delegate from such state.

Article 4. Meetings

- 4.1. All meetings of the House of Delegates shall be open unless the House of Delegates, by a vote of two-thirds of the total House, as defined in Section 7.1 of the Bylaws, votes to go into executive session. When in executive session, the following only shall be admitted to the room in which the meeting is held: members of the House

of Delegates (as defined in Section 7.1 of the Bylaws), the parliamentarian, and others specifically authorized by a majority vote of the House of Delegates.

Article 5. Open Hearing

5.1. An open hearing shall be conducted, in conjunction with any in-person House of Delegates session, to provide a forum for members to express their opinions on matter of concern to them and on matters to be considered by the House of Delegates.

5.1.1. At the call of the Chair of the House of Delegates, and with approval of the Board of Directors, additional open hearings may be scheduled.

5.1.2. The Chair of the House of Delegates shall preside at any open hearing and may request assistance from members of the Board of Directors, officers of the Society, and council Chairs.

Article 6. Privilege of the Floor

6.1. The privilege of the floor (which may include the right to participate in debate on a matter), during a meeting of the House of Delegates, may be extended by either the Chair or the House of Delegates.

Article 7. Conduct of Business of the House

7.1. The Business of the House of Delegates shall be as follows, unless the Chair of the House of Delegates determines that the business or matters for the House require a different order or that additional items to the order are required:

- a. Call to order.
- b. Roll call of delegates.
- c. Reports of officers and the Board of Directors.
- d. Recommendations of delegates.
- e. Reports of councils and committees.
- f. Resolutions.
- g. Unfinished business.
- h. New business.
- i. Triennial Election of the Chair of the House of Delegates.
- j. Installation of officers and Directors.
- k. Adjournment.

7.2. Any matter upon which action is to be taken by the House of Delegates will be presented to delegates in writing and in advance. The Secretary will distribute copies of the proposed action to the House. Action of the House is, at all times, subject to Section 7.3 and, in particular, Section 7.3.1.3 of the Bylaws.

7.2.1. Any matter to be presented as new business shall be presented to the Chair of the House in writing no later than four o'clock in the evening before the day of the meeting in which new business is on the agenda. If any such matter will include the offering of a motion, the writing required by this rule shall state explicitly the motion to be offered.

7.2.2. Resolutions to be considered by the House of Delegates must be presented in writing to the Secretary of the House of Delegates at least 90 days in advance of the session and be signed by at least two active members of ASHP.

7.2.2.1. Resolutions not voluntarily withdrawn by the submitter that meet the requirements of the governing documents shall be presented to the House of Delegates by the Committee on Resolutions at the first meeting and acted upon at the second meeting. They shall be submitted to delegates with one of the following recommendations: (a) recommend adoption, (b) do not recommend adoption, (c) recommend referral for further study, or (d) presented with no recommendation of the Committee on Resolutions.

Action by the House of Delegates shall be on the substance of the resolutions and not on the recommendation of the Committee on Resolutions.

7.2.2.2. The House shall be informed of resolutions not presented to it and the reasons therefore.

7.3. Any item presented for action by the House of Delegates shall, unless the Bylaws or these rules specify to the contrary, require for passage the vote required by *Robert's Rules of Order*. Except for election of the Chair, no vote shall be by secret ballot.

7.3.1. Any matter not acted upon by the House of Delegates, upon adjournment of the session, shall die.

7.4. Matters of an emergent nature must be acted upon in accord with Section 7.3.1.3. of the Bylaws.

Article 8. Nominations and Elections

8.1. Nominations of Directors of ASHP (including the Chair of the House of Delegates) shall be by the Committee on Nominations in accordance with Section 7.4 of the Bylaws.

8.1.1. A written biography on each nominee shall be prepared and distributed at the appropriate meeting of the House of Delegates session.

8.1.2. The Chair shall appoint three delegates to serve as election tellers for elections conducted in the House of Delegates. Tellers shall supervise the election, count ballots, and report to the Chair the results thereof. The Chair shall share the election results with each nominee but shall announce only the name of the candidate receiving the majority of votes cast for Chair of the House of Delegates.

8.1.3. The Chair shall be elected by written or electronic secret ballot of the House of Delegates and need receive only a majority of votes cast.

8.1.4. The Committee on Nominations shall issue a separate report containing two nominees for each Director and the office of President-elect.

Article 9. Amendments

9.1. Every proposed amendment to the Rules of Procedure for the House of Delegates shall be submitted in writing at one meeting of the House of Delegates and may be acted upon at a subsequent meeting of the session, when upon receiving a majority

of votes cast, it shall become a part of these rules, effective as of the following session of the House of Delegates.

Developed by the ASHP Council on Organizational Affairs. Approved by the ASHP Board of Directors, November 20–21, 1985, and by the ASHP House of Delegates, June 4, 1986. Supersedes the previous document, Regulations for the ASHP House of Delegates. Revised by the ASHP Board of Directors and approved by the ASHP House of Delegates, June 3, 2014. Supersedes previous versions of this document.

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The Next Generation of Learning

ASHP House of Delegates 2014
June 1 and 3, 2014

REPORT ON IMPLEMENTATION OF 2013

ASHP HOUSE OF DELEGATES ACTIONS AND RECOMMENDATIONS

Council on Pharmacy Management A (1301): Payer Processes for Payment Authorization and Coverage Verification

To advocate that public and private payers collaborate with each other and with health care providers to create standardized and efficient processes for authorizing payment or verifying coverage for care; further, To advocate that payment authorization and coverage verification processes (1) facilitate communication among patients, providers, and payers prior to therapy; (2) provide timely payment or coverage decisions; (3) facilitate access to information that allows the pharmacist to provide prescribed medications and medication therapy management to the patient; and (4) foster continuity in patient care.

This policy has been published in ASHP's *Best Practices for Hospital and Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP provided testimony at the FDA hearings in the fall 2013 on REMS and the impact prior authorizations are having on access to medications for patients and continuity of care. ASHP has included in Midyear and Conference for Leaders in Health-System Pharmacy educational programming specifically highlighting best practices in discharge process management, including models in which health-system pharmacists have improved the prior authorization. ASHP continues its involvement with the Pharmacy HIT Collaborative, which works to ensure health-system pharmacy's interests are addressed in the development of EHRs and the associated information exchanges necessary for transitions of care. Additionally, ASHP and the Academy of Managed Care Pharmacy (AMCP) are working together on an initiative to improve the communication of critical information to facilitate transitions of care.

Council on Pharmacy Management B (1302): Interoperability of Patient-Care Technologies

To encourage interdisciplinary development and implementation of technical and semantic standards for health information technology (HIT) that would promote the interoperability of patient-care technologies that utilize medication-related databases (e.g., medication order processing systems, automated dispensing cabinets, intelligent infusion pumps, electronic health records); further,

To encourage the integration, consolidation, and harmonization of medication-related databases used in patient-care technologies to reduce the risk that outdated, inaccurate, or conflicting data might be used and to minimize the resources required to maintain such databases.

This policy has been published in ASHP's *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to participate in the Pharmacy HIT Collaborative, which works to ensure health-system pharmacy's interests are addressed in the development of EHRs and the associated information exchanges necessary for transitions of care and whose work is supported by the Section of Pharmacy Informatics and Technology. To help advance pharmacists' roles in achieving interoperability of patient-care technologies, ASHP has developed the Informatics Institute for the Summer Meetings and launched the Pharmacy Informatics Essentials distance learning programs. ASHP also has submitted comments on track-and-trace standards, advocating that they support interoperability.

Council on Pharmacy Management C (1303): Proliferation of Accreditation Organizations

To advocate that health care accreditation organizations include providers and patients in their accreditation and standards development processes; further,

To encourage health care accreditation organizations to adopt consistent standards for the medication-use process, based on established principles of patient safety and quality of care; further,

To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation organizations.

ASHP continues to work closely with accreditation organizations and has health-system representatives on a number of advisory committees with The Joint Commission (TJC). ASHP has provided consultation to TJC that has influenced development or changes in standards and national patient safety goals, as well as a webinar to TJC surveyors on new compounding legislation. ASHP continues to work on influencing the updating process for the CMS Conditions of Participation. ASHP is also a leading partner with the American Pharmacists Association (APhA) and the National Association of Boards of Pharmacy (NABP) in the Center for Pharmacy Practice Accreditation (CPPA), a 501 (c) (6) nonprofit organization that is developing and implementing comprehensive programs of pharmacy practice site accreditation. In the fall of 2013, CPPA announced the development of an accreditation program for specialty pharmacy practices.

Council on Pharmacy Management D (1304): Drug Product Reimbursement

To pursue, in collaboration with public and private payers, the development of improved methods of reimbursing pharmacies for the costs of drug products dispensed, compounding and dispensing services, and associated overhead; further,

To educate pharmacists about those methods.

This policy has been published in ASHP's *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP routinely submits comments to CMS on the updates to the IPPS and HOPPS proposed rules notifications and any changes proposed to ASP pricing models. ASHP presents an education session on the changes to these rules annually at the Midyear. Additionally at the 2014 Conference for Leaders in Health-System Pharmacy there will be an intensive workshop provided for participants on medication reimbursement and associated compliance and regulatory issues.

Council on Pharmacy Practice A (1305): Education About Performance-Enhancing Substances

To encourage pharmacists to engage in community outreach efforts to provide education to athletes on the risks associated with the use of performance-enhancing substances; further,

To encourage pharmacists to advise athletic authorities and athletes on the dangers of performance-enhancing substances and other products that are prohibited in competition; further,

To advocate for the role of the pharmacist in all aspects of sports doping control.

This policy has been published in ASHP's *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. Other specific actions are under consideration.

Council on Pharmacy Practice B (1306): Standardization of Intravenous Drug Concentrations

To develop nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given as continuous infusions to adult and pediatric patients; further,

To encourage all hospitals and health systems to use infusion devices that interface with their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities; further,

To encourage interprofessional collaboration on the adoption and implementation of standardized drug concentrations and dosing units in hospitals and health systems.

ASHP, in collaboration with the FDA and Association for the Advancement of Medical Instrumentation (AAMI), has been engaged in standardization efforts for the past two years. A preliminary list of drugs and standardized concentrations was completed in March 2014. This list is being used to survey hospitals to determine whether converting to the standardized concentrations is feasible. The final list will be published and a communication plan promoting standardization will be launched later in 2014.

Council on Pharmacy Practice C (1318): ASHP Statement on the Pharmacist’s Role in Substance Abuse Prevention, Education, and Assistance

To approve the [ASHP Statement on the Pharmacist’s Role in Substance Abuse Prevention, Education, and Assistance](#).

The statement has been published in ASHP’s *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and *AJHP*, and has been used in ongoing ASHP advocacy, education, and communication efforts. Other specific actions regarding abuse of prescription drugs are underway.

Council on Public Policy A (1307): Pharmacist Recognition as a Health Care Provider

To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as health care providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as health care providers, improve access to patient care and bridge existing gaps in health care; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

To pursue a standard mechanism for compensating pharmacists who provide these services.

ASHP is actively participating in the [Patient Access to Pharmacists’ Care Coalition](#), which recently succeeding in getting [H.R. 4190](#) introduced in the U.S. House of Representatives. Other [activities on this issue](#) by ASHP include advocating for inclusion of pharmacists as professionals within Medicare accountable care organizations (ACOs) and supporting state affiliate advocacy for state provider status legislation.

Council on Public Policy B (1308): Compounding by Health Professionals

To advocate that state laws and regulations that govern compounding by health professionals adopt the applicable standards of the *United States Pharmacopeia*.

ASHP was successful in obtaining passage of the [Drug Quality and Security Act](#) (P.L. 113-54) that clarifies compounding by pharmacies and creates regulatory requirements for outsourcing facilities. This policy will continue to be used in [ongoing advocacy](#) with the FDA as it develops compounding regulations under this new provision of the Food, Drug & Cosmetic Act.

Council on Public Policy C (1309): Pharmacists’ Role in Immunization and Vaccines

To affirm that pharmacists have a role in improving public health and increasing patient access to immunizations by promoting and administering appropriate immunizations to patients and employees in all settings; further,

To collaborate with key stakeholders to support the public health role of pharmacists and student pharmacists in the administration of adult and pediatric immunizations; further,

To advocate that states grant pharmacists and appropriately supervised student pharmacists the authority to initiate and administer all adult and pediatric immunizations; further,

To advocate that pharmacists and student pharmacists who have completed a training and certification program acceptable to state boards of pharmacy and meeting the standards established by the Centers for Disease Control and Prevention may provide such immunizations; further,

To advocate that state and federal health authorities establish centralized databases for documenting

administration of immunizations that are accessible to all health care providers; further,
 To advocate that state and federal health authorities require pharmacists and other immunization providers to report their documentation to these centralized databases, if available; further,
 To strongly encourage pharmacists to educate all patients, their caregivers, parents, guardians, and health care providers about the importance of immunizations for disease prevention; further,
 To encourage pharmacists to seek opportunities for involvement in disease prevention through community immunization programs; further,
 To advocate for the inclusion of pharmacist-provided immunization training in college of pharmacy curricula.

This policy continues to be used in ongoing advocacy at the state level.

Council on Public Policy D (1310): Regulation of Telepharmacy Services

To advocate that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of United States-based telepharmacy services; further,
 To advocate that boards of pharmacy and state agencies that regulate pharmacy practice include the following in regulations for telepharmacy services: (1) education and training of participating pharmacists; (2) education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating pharmacy technicians; (3) communication and information systems requirements; (4) remote order entry, prospective order review, verification of the completed medication order before dispensing, and dispensing; (5) direct patient-care services, including medication therapy management services and patient counseling and education; (6) licensure (including reciprocity) of participating pharmacies and pharmacists; (7) service arrangements that cross state borders; (8) service arrangements within the same corporate entity or between different corporate entities; (9) service arrangements for workload relief in the point-of-care pharmacy during peak periods; (10) pharmacist access to all applicable patient information; and (11) development and monitoring of patient safety, quality, and outcomes measures; further,
 To identify additional legal and professional issues in the provision of telepharmacy services to and from sites located outside the United States.

This policy has been used in ongoing ASHP advocacy and communications related to telepharmacy.

Council on Public Policy E (1311): Regulation of Centralized Order Fulfillment

To advocate changes in federal and state laws, regulations, and policies to permit centralized medication order fulfillment within health care facilities under common ownership.

This policy continues to be used in ongoing advocacy at the state level.

Council on Therapeutics A (1312): Medication Overuse

To define medication overuse as use of a medication when the potential risks of using the drug outweigh the potential benefits for the patient; further,
 To recognize that medication overuse is inappropriate and can result in patient harm and increased overall health care costs; further,
 To advocate that pharmacists take a leadership role in interprofessional efforts to minimize medication overuse.

This policy has been published in ASHP's *Best Practices for Hospital and Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP is currently seeking authors to draft a statement that would increase awareness of medication overuse and provide strategies for addressing this issue.

Council on Therapeutics B (1313): Drug-Containing Devices

To recognize that use of drug-containing devices (also known as combination devices) has important clinical and safety implications for patient care; further,

To advocate that use of such devices be documented in the patient's medical record to support clinical decision-making; further,

To encourage pharmacists to participate in interprofessional efforts to evaluate and create guidance on the use of these products through the pharmacy and therapeutics committee process to ensure patient safety and promote cost-effectiveness; further,

To advocate that the Food and Drug Administration (FDA) and device manufacturers increase the transparency of the FDA approval process for drug-containing devices, including access to data used to support approval; further,

To encourage research that evaluates the clinical and safety implications of drug-containing devices to inform product development and guide clinical practice.

This policy has been published in ASHP's *Best Practices for Hospital and Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. Other specific actions are under consideration.

Council on Therapeutics C (1314): DEA Scheduling of Hydrocodone Combination Products

To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone combination products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

ASHP submitted comments to FDA calling for rescheduling of hydrocodone-containing products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential in These comments were submitted in advance of a public meeting of FDA's Drug Safety and Risk Management Advisory Committee that was held in October 2012. That meeting was in response to DEA's request for an evaluation and Congress' directive that FDA consider this issue. In November 2013, ASHP sent a letter to Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services urging the FDA to move forward with reschedule hydrocodone-containing combination products as recommended by the advisory committee, which voted 19 to 10 in favor of rescheduling this therapy in January 2013.

Council on Therapeutics D (1315): DEA Scheduling of Controlled Substances

To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current evidence concerning the abuse potential of these therapies; further,

To monitor the effect of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact on patient access to these medications and on the practice burden of health care providers.

In April 2014, ASHP provided comments to DEA in response to the Agency's proposal to reclassify hydrocodone-containing products to Schedule II. In addition, ASHP commented on the DEA's clarification of the scheduling process by calling for clear, measurable criteria and a transparent process as described in this policy.

Council on Education and Workforce Development A (1316): Pharmacy Resident and Student Roles in New Practice Models

To promote pharmacy practice and training models that: (1) provide experiential and residency training in team-based patient care; (2) recognize and utilize the skills and knowledge of student pharmacists and residents in providing direct patient care services; (3) augment the patient care services of pharmacists through expanded roles for residents as practitioner learners; and (4) where appropriate, utilize an

approach to learning and service in which a supervising pharmacist oversees the services of students, residents, and other pharmacists providing direct patient care; further,

To support the assessment of the impact of these pharmacy practice and training models on the quality of learner experiences and patient care outcomes.

This policy has been published in ASHP's *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. In addition, PGY1 residency standards are in process of revision, the National Pharmacy Preceptors Conference is now an annual event, and a partnership has been formed with University of Kentucky for a series of 31 short distance learning modules, *Preceptor's Playbook: Tactics, Techniques & Strategies*, for preceptor development available at <http://elearning.ashp.org/>.

Council on Education and Workforce Development B (1317): Education and Training in Health Care Informatics Pharmacy

To recognize the significant and vast impacts of health-system information systems, automation, and technology changes on safe and effective use of medications; further,

To foster, promote, and lead the development of and participation in formal health care informatics educational programs for pharmacists, pharmacy technicians, and student pharmacists.

This policy has been published in ASHP's *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. In addition, *Pharmacy Informatics Essentials*, a series of 16 distance learning modules, has been developed as a comprehensive package which will be available at <http://elearning.ashp.org/> and a new conference entitled *Informatics Institute (I²)* will be offered within the ASHP Summer Meetings.

Section of Pharmacy Informatics and Technology (1319): ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics

To approve the *ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics*.

The statement has been published in ASHP's *Best Practices for Hospital & Health-System Pharmacy* (print and online editions) and has been shared with pharmacy technician organizations.

Enhancing the Value of Experiences for Student Pharmacists (New Business): Dennis Williams (NC), Scott Meyers (IL)

ASHP should work with the appropriate entities (e.g., ACPE, NABP, and State Boards of Pharmacy) to optimize the professional practice-related experiences of student pharmacists working under the supervision of pharmacists.

The Council on Education and Workforce Development considered the New Business item at its September meeting (see Other Council Activity). Although the Council supported the intent of the new business item, it decided against creating new policy (including reinstating ASHP policy 1204) or revising existing policy.

Pharmacy Performance Measures (Recommendation): Jerome Wohleb (NE, SOPIT), Kevin Marvin, Michele Faulkner, Donna Soflin, Melinda Burnworth, Dennis Williams, Julie Lienhart, Erin Christensen, Joseph Aloï

To advocate for and lead development and refinement of standard outcome and performance measures to support the value of pharmacists as health care providers as a replacement for existing productivity metrics.

The issue of health system pharmacy practice metrics has been part of regular discussions and efforts of ASHP's Council of Pharmacy Management and the Section of Pharmacy Practice Managers for the past few years. In an effort to help define the issues and provide guidance to ASHP members Section leaders published the "Effective use of workload and productivity monitoring tools in health-system pharmacy" (Part One and Two) in AJHP. In addition we saw language change to ASHP policy in 2009 that strengthened the position of ASHP's policy as it related to workload and productivity; Workload Monitoring and Reporting (0901).

In May 2011, the Section finalized and posted a series of five slide presentations based on the paper to be

used by members in educating the C-suite, peers, and pharmacy staff on workload and productivity:

<http://www.ashp.org/menu/MemberCenter/SectionsForums/SPPM/Resources.aspx>

Also, during the Pharmacy Practice Model Initiative Summit the recommendation was made to develop a health system pharmacy sensitive complexity tool. This work is under way and practitioners from other health professions with experience in working with case management, medicine, and nursing complexity indexes will be included in the development. The process will incorporate evidenced-based research of key factors to be considered in making patient care decisions. While this PPMI complexity tool will not result in specific metrics it will be a key step towards identifying the critical factors needed to be incorporated into patient care prioritization based on local hospital data, as well as factors necessary to take into consideration in developing measures and metrics. This process will result in a profession-endorsed tool utilizing evidenced based information.

In addition, the ASHP Pharmacy-Sensitive Accountability Measures workgroup has developed a set of “Proposed Quality Measures Recommended by the ASHP Pharmacy-Sensitive Accountability Measures” that is in press at *AJHP*. The work group was established in response to the Council on Pharmacy Management’s request to review and/or establish measures that reflect the quality and outcomes of pharmacy services. The goal of the work group was to identify measures that establish accountability and demonstrate the value of health-system pharmacists in keeping patients safe, and improving outcomes, as well to identify a suite of measures that address preventable harms in the inpatient and outpatient settings (e.g., adverse drug events, drug related hospital (re)admissions) that can be adopted universally on pharmacy dashboards to reflect pharmacy accountability. Information on their work and outcomes is available at the URLs below:

ASHP PSAM Background: https://ashp.qualtrics.com/CP/File.php?F=F_b9jqFFspOiksVNP

PSAM Measures Information Detail: https://ashp.qualtrics.com/CP/File.php?F=F_9Le4pwLRdRTdg2N

Flexibility for State Delegations (Recommendation): Scott Meyers (IL)

ASHP’s Task Force on Organizational Structure should develop a mechanism within the rules of the House whereby very engaged State delegations may, to coin a WWE term, “Tap In and Tap Out” alternate delegates for the purpose of discussion of specific agenda items for which an alternate delegate may be more engaged than a sitting delegate.

The final meeting of the Board’s Task Force on Organizational Structure was July 19, 2013. This recommendation was provided to the Task Force as part of their background, and they discussed the feasibility of allowing delegates and alternate delegates the flexibility of modifying their delegate status during the House meetings. The Task Force’s proposal is that alternate delegates would be invited to participate in all activities of the House of Delegates, including voting on proposed policies, but that alternate delegate votes would not be recorded as official votes unless necessary (i.e., the state delegates did not vote). The intent of this was to engage alternate delegates to the same extent as voting delegates. This process was envisioned for the electronic version of the House of Delegates; the Task Force did not discuss this in terms of the face-to-face House meetings. It should be noted, however, that the Chair of the House has discretion to recognize any individual, delegate or not, to address the House.

Pharmacy Benchmark Metrics to Support C-Suite Healthcare Reform Goals (Recommendation): Melinda Burnworth (AZ), Erin Christensen (SD), Jerome Wohleb (NE)

Identify and standardize metrics used to support outcome measures that support ongoing pharmacist value to replace current methods and metrics for productivity and clinical outcomes.

The issue of health system pharmacy practice metrics has been part of regular discussions and efforts of ASHP’s Council of Pharmacy Management and the Section of Pharmacy Practice Managers for the past few years. In an effort to help define the issues and provide guidance to ASHP members Section leaders

published the “Effective use of workload and productivity monitoring tools in health-system pharmacy” (Part One and Two) in AJHP. In addition we saw language change to ASHP policy in 2009 that strengthened the position of ASHP’s policy as it related to workload and productivity; Workload Monitoring and Reporting (0901).

In May 2011 the Section finalized and posted a series of five slide presentations based on the paper to be used by members in educating the C-suite, peers, and pharmacy staff on workload and productivity:

<http://www.ashp.org/menu/MemberCenter/SectionsForums/SPPM/Resources.aspx>

Also, during the Pharmacy Practice Model Initiative Summit, the recommendation was made to develop a health system pharmacy sensitive complexity tool. This work is under way and practitioners from other health professions with experience in working with case management, medicine, and nursing complexity indexes will be included in the development. The process will incorporate evidenced based research of key factors to be considered in making patient care decisions. While this PPMI complexity tool will not result in specific metrics it will be a key step towards identifying the critical factors needed to be incorporated into patient care prioritization based on local hospital data, as well as factors necessary to take into consideration in developing measures and metrics. This process will result in a profession endorsed tool utilizing evidenced based information.

In addition, the ASHP Pharmacy-Sensitive Accountability Measures workgroup has developed a set of “Proposed Quality Measures Recommended by the ASHP Pharmacy-Sensitive Accountability Measures”. The work group was established in response to the Council on Pharmacy Management’s request to review and/or establish measures that reflect the quality and outcomes of pharmacy services. The goal of the work group was to identify measures that establish accountability and demonstrate the value of health-system pharmacists in keeping patients safe, and improving outcomes, as well to identify a suite of measures that address preventable harms in the inpatient and outpatient settings (e.g., adverse drug events, drug related hospital (re)admissions) that can be adopted universally on pharmacy dashboards to reflect pharmacy accountability. For information on their work and outcomes please see below:

ASHP PSAM Background: https://ashp.qualtrics.com/CP/File.php?F=F_b9jqFFspOiksVNP

PSAM Measures Information Detail: https://ashp.qualtrics.com/CP/File.php?F=F_9Le4pwLRdRTdg2N

Creation of Model Credentialing for Pharmacist Provider (Recommendation): Adam Porath (NV)

[That ASHP create a model credentialing for pharmacist providers.](#)

The suggestion to create a credentialing model for pharmacist providers is a good one. A high-level framework for that has been developed by the Council on Credentialing in Pharmacy (see links below). ASHP is also working with the [Patient Access to Pharmacists’ Care Coalition](#) to advocate for pharmacists as providers in Medicare and Medicaid; some of this work will likely lead to further elaboration on credentials and credentialing.

<http://www.pharmacycredentialing.org/Files/CCPWhitePaper2010.pdf>

<http://www.pharmacycredentialing.org/Files/GuidingPrinciplesPharmacistCredentialing.pdf>

Statement on the Pharmacist’s Role in Informatics (Recommendation): Trish Wegner, Despina Kotis (IHP)

[That ASHP, through the Section of Pharmacy Informatics, review and update the ASHP Statement on the Pharmacist’s Role in Informatics, adopted in 2006.](#)

The Section of Pharmacy Informatics and Technology is in process of revising this statement. The Section Advisory Group on Professional Development conducted a survey to evaluate roles and scope of practice of pharmacists involved in informatics, technology, and automation in spring of 2013. The Advisory Group reviewed the survey findings and made some recommendations. Once the survey results were summarized,

the Advisory Group began work on revising the statement. A draft was circulated for peer review in February, and a final draft is expected by the December 2014.

Guidelines for the Prescribing of Appropriate Quantities of Controlled Substances (Recommendation): John Pastor, Jamie Sinclair, Paul Wittmer (MN)

That ASHP advocate for development of guidelines promoting the prescribing of appropriate quantities of controlled substances to patients.

This recommendation was discussed by the Council on Therapeutics (COT) at its September meeting (see Board Actions). The Council recommended and the Board voted to collaborate with interdisciplinary stakeholders to develop, disseminate, and encourage adoption of practice-based strategies that address the public health epidemic of prescription drug abuse.

Campaign on the Value of Pharmacists (as Care Providers) (Recommendation): Steve Riddle (SACP)

That ASHP engage relevant stakeholders and explore the creation of a national marketing campaign that communicates the value of pharmacists to increase the awareness of and demand for pharmacy care services.

ASHP is involved in a profession-wide campaign to achieve provider status. It is important to recognize that a campaign of this nature cannot be successful at the national level without a great deal of state and local level campaigning. Fundamentally, the public and patients need to experience--in their communities--what we are describing through a national campaign, and pharmacists need to be strong and consistent media and political spokespeople in their communities. ASHP and other organizations can provide training, materials, and resources, but at the end of the day, the messages and the people delivering them need to focus mostly on the local and state levels.

Creation of Pharmacy Practice Registries (Recommendation): Steve Riddle (SACP)

That ASHP investigate the feasibility and value of creating pharmacy practice registries (databases) that foster the exchange of information that supports practice advancement.

The Executive Committee of the Section of Ambulatory Care Practitioners explored the feasibility of creating pharmacy practice registries and concluded that the resources required are not available.

Training of Preceptors (Recommendation): Donald Lynx (IL)

That ASHP work with the appropriate organizations to develop standards and criteria in order to be a preceptor providing IPPE or APPE rotations for pharmacy students.

ASHP has discussed the issue of training sites and preceptor qualifications at the Deans Meeting held at the ASHP Midyear Clinical Meeting for the last two years. ASHP also continues to develop preceptor training materials and post such materials on our Preceptor Skills Resource Center, and in addition ASHP has made the National Pharmacy Preceptor Conference an annual event. The need for standards for preceptors will be included in ASHP's comments to Accreditation Council for Pharmacy Education on its latest draft standards for accreditation of colleges and schools of pharmacy.

Adjudication of Resident Concerns (Recommendation): Christi Jen, Melinda Burnworth, Carol Rollins (AZ)

That ASHP develop a formal mechanism for addressing resident concerns confidentially, without repercussions, and expediently through an ASHP forum (e.g., New Practitioner Forum).

ASHP has examined this recommendation and concluded that the New Practitioner Forum is not the best venue for addressing residents' concerns about residency programs. ASHP offers a formal complaint process regarding ASHP accredited training programs through the accreditation services division. This process may begin with an anonymous inquiry to the ASHP Director of Accreditation Services, and the name of the complainant remains confidential until a formal complaint is filed.

Pharmacist's Role in Pharmacogenomics (Recommendation): Sam Calabrese (OH), James Hoffman (TN)

That ASHP assess the impact of next-generation genomics on health-system pharmacy and develop a statement on the pharmacist's role in pharmacogenomics to assist in optimal medication use.

The Section of Clinical Specialists and Scientists Executive Committee Section Advisory Group on Emerging Sciences has developed a statement on this topic for the House’s consideration at this session.

Future Meeting Location (Recommendation): Casey White (TN)

That ASHP take a serious and in-depth look at Nashville as a future Summer Meeting location.

ASHP understands the importance of rotating the host city of our various meetings, conferences, and specialty courses each year. ASHP will explore the potential viability of this venue for one of our meetings. Several criteria are considered in selecting a location and must be kept in mind, along with other intangibles:

- geography
- ease of access for travel
- venue – meeting space and hotel access
- availability of preferred dates
- price
- previous experience/evaluation data
- potential for weather impacting success of meeting

Taskforce on Compounding (Recommendation): Lynn Eschenbacher (SCIP, SACP, SOPIT, SPMI)

That ASHP develop guidance on stability and sterility testing and how to determine which laboratories to trust related to insourced and outsourced compounded medications.

ASHP is evaluating member resource needs in light of the recent meningitis outbreak that resulted from contaminated sterile products and pending FDA regulations. A team of staff from multiple ASHP divisions is meeting regularly to discuss specific information needs and develop plans to address identified areas. This recommendation for guidance on determining stability and sterility for sterile products has been shared with this team. In addition, ASHP recently conducted a member survey to assess compounding and outsourcing practices. That survey is one of several mechanisms that ASHP is using to gather member feedback to assist in developing potential resources, which may include guidelines, educational programs, journal articles, or print or electronic publications. Given the rapidly changing regulation of compounding, ASHP cannot at this time offer detailed advice along the lines of this recommendation, but as soon as FDA regulations are finalized ASHP will evaluate the options for providing our members information and will provide guidance, tools, and other resources.

Summer Meeting Location (Recommendation): Dan Degnan, John Hertig, Amy Hyduk (IN)

That ASHP consider Indianapolis as a future Summer Meeting location.

ASHP understands the importance of rotating the host city of our various meetings, conferences, and specialty courses each year. ASHP will explore the potential viability of this venue for one of our meetings. Several criteria are considered in selecting a location and must be kept in mind, along with other intangibles:

- geography
- ease of access for travel
- venue – meeting space and hotel access
- availability of preferred dates
- price
- previous experience/evaluation data
- potential for weather impacting success of meeting

Essential Role of the Pharmacy Technician (Recommendation): Tricia Killingsworth (SCIP, SPPM)

That ASHP develop a policy defining the essential roles of the pharmacy technician in managing technology, supply chain, and data management (IT) to support the advancement of pharmacy practice.

A work group from the Section of Inpatient Care Practitioners Section Advisory Group on Pharmacy Technicians and Support Services is developing a draft statement and plans to conclude work on it by December 2014.

Sterile Compounding Tools (Recommendation): Leigh Fritz (UT)

That ASHP develop specific tools to help health systems meet USP Chapter 797 requirements for extended beyond-use dating.

ASHP is evaluating member resource needs in light of the NECC compounding tragedy and rapidly changing regulation of compounding. A team of staff from multiple ASHP divisions is meeting regularly to discuss specific information needs and develop plans to address identified areas. The recommendation for guidance to assist health systems in establishing extended beyond-use dating (BUD) has been shared with this team. ASHP does have a publication that addresses some aspects of this topic: Extended Stability for Parenteral Drugs. However, the team will consider whether additional information, such as guidelines outlining general principles for establishing BUD, would be useful to practitioners.

Centralized Pharmacy Services (Recommendation): Missy Skelton Duke (UT)

That ASHP develop a list of standardized terminology and definitions related to central pharmacy services, including but not limited to order processing, preparation, compounding, repackaging, and other distributive functions.

As hospitals and health systems continue to acquire and merge, the drive to centralize services and functions has become increasingly important to our pharmacy leaders and their C-suites. This recommendation is very timely, as centralization is currently one of the top concerns of the Section of Pharmacy Practice Managers Advisory Group on Multi-Hospital Health System Pharmacy Executives. The Advisory Group has not been discussing directly the need to create definitions of different types of centralized services, but has been discussing best practices. This recommendation was shared with the Advisory Group for their consideration in the fall of 2013. The challenges and issues related to centralization of pharmacy services and functions for health systems was a topic of the Council on Pharmacy Management (CPM) at its 2013 meeting (see CPM Policy Recommendation B and Other Council Activity).

Regulation of Advanced Practice (Recommendation): Steve Gray (CA)

That ASHP create a task force to make recommendations about how Boards of Pharmacy should regulate the advanced practice of pharmacy that has traits more like medical practice.

The Council on Public Policy and the Council on Pharmacy Practice jointly considered the topic of gaps in the current National Association of State Boards of Pharmacy (NABP) Model State Pharmacy Act and Model Rules (see the "Other Council Activity" section of their Board reports). The Councils concluded that a review of the Model Act and perhaps other representative state practice acts should be conducted to identify elements that need to be developed by ASHP and ultimately used by state affiliates in their advocacy before state legislatures and boards of pharmacy to help achieve members' goals, including regulation of advanced pharmacy practice. The Councils agreed to identify these provisions, develop a document that would make the case for needed changes, and develop specific model language based on that document.

Conflict with Affiliate Business Ventures (Recommendation): Scott Meyers (IL)

That the ASHP Board of Directors and staff conscientiously consider the financial/relational impact of initiating new business ventures that compete with established programs of its affiliates.

ASHP has a strong interest in the success of its state affiliates and devotes considerable resources to maintaining and strengthening those relationships. Many considerations go into a decision to launch a new ASHP venture, and we will continue to evaluate the impact of new initiatives on state affiliates, seeking partnerships as appropriate.

Timing of ASHP Foundation Breakfast (Recommendation): Eric Hola (NJ)

That ASHP make arrangements for the ASHP Foundation Donor Recognition Breakfast to start at a more reasonable hour than 6:30 a.m.

The timing of events at ASHP meetings is often dictated by the need to avoid conflicts with participants' schedules. Although the time of the ASHP Foundation Donor Recognition Breakfast could not be changed for

the 2014 meeting, ASHP Foundation and ASHP staff will continue to examine alternatives that will allow for the broadest participation and the least inconvenience.

Exhibitions at Summer Meeting (Recommendation): Frank Sosnowski (NY)

That ASHP explore a reverse expo format during the ASHP Summer Meeting.

ASHP is currently exploring the feasibility of a reverse expo at the Summer Meeting and evaluating the impact it may have on the overall success of the meeting.

Large Residency Programs (Recommendation): Stephen Eckel (NC)

That ASHP develop a different organizational structure to assist in local management of large pharmacy residencies.

The ASHP Commission on Credentialing is revising the PGY1 residency standard and is specifically taking into consideration the unique needs of large residency programs. Examples include mechanisms that allow delegation of residency program director duties to others, and other potential ways to reduce the administrative burden of administering residency programs.

Task Force on Science, Technology, and Genomics (Recommendation): James Hoffman (TN)

That ASHP evaluate the need for a task force on science and technology (especially genomics) so health-system pharmacists are positioned as leaders in the introduction of new technologies into health care.

A top priority for ASHP is developing tools and resources for members practicing in pharmacogenomics and personalized medicine. Past efforts include the 1998 and 2008 Task Force on Science, with current implementation of the latest Task Force Recommendations. Current ASHP efforts and resources for pharmacists in the area of pharmacogenomics include an official policy on pharmacogenomics, an Advisory Group on Emerging Sciences in the Section of Clinical Specialists and Scientists (which developed the statement on pharmacogenomics being considered by the House at this session), an Emerging Sciences Resource Center, endorsement of CPIC guidelines and, beginning this year, an Emerging Sciences networking session at the Midyear Clinical Meeting. Also, the ASHP pharmacy practice model initiative (PPMI) contains a consensus statement stating that adjustment of medication regimens based on genetic characteristics of the patient should be considered essential to pharmacist provided drug-therapy management in optimal pharmacy practice models. ASHP will evaluate potential needs and resource requirements for a Task Force on Science, Technology, and Genomics while also considering alternatives such as utilizing key networks within ASHP that contain members with expertise in the specific practice areas suggested. The recommendation will continue to be discussed by the Section of Clinical Specialists and Scientists Executive Committee and Advisory Group on Emerging Sciences with consideration of including ideas in future Advisory Group charges.

Creation of Pharmacy Simulation Research Grants (Recommendation): Daniel Degnan, John Hertig (IN)

That ASHP work with the ASHP Research and Education Foundation to develop, administer, and fund pharmacy simulation research grants.

The ASHP Foundation funds research focusing on new investigator development and on practice model advancement. Grants typically are in the \$5-50,000 range. Research grant proposals that include pharmacy simulation modeling would be actively considered in one of the Foundation's existing grant programs (<http://www.ashpfoundation.org/MainMenuCategories/ResearchResourceCenter/FundingOpportunities>). The Foundation does not have funding capacity to devote a dedicated research grant program to the subject of pharmacy simulation research. The Foundation staff welcomes further discussion of the recommendation to determine if there are opportunities to seek funding from other potential collaborating corporations or foundations.

Defined Criteria for Becoming a New ASHP Section (Recommendation): Daniel Degnan, John Hertig (IN)

That ASHP clearly define the path to establishing new ASHP Membership Sections for new and emerging pharmacy specialties.

The Task Force discussed the recommendation at its final meeting on July 19, 2013. The Task Force preferred to establish a broader goal of encouraging an evolutionary pathway by which member segments could demonstrate success rather than develop a proscriptive pathway that could potentially stimulate numerous requests for new Sections or Forums that ASHP could not support. Member segment success would provide the ASHP Board of Directors with the information needed (e.g., membership size, level of engagement, unique membership service needs, overall contribution to ASHP) to make decisions about investments in additional resources or structure. The Task Force concluded that at this time online communities have the best potential to support the future growth, development, and leadership opportunities for emerging practice areas.

PhRMA Direct-to-Consumer Medication Distribution (Recommendation): Amy Hyduk, Daniel Degnan, John Hertig (IN)

That ASHP review recent manufacturer-initiated distribution pathways that sell medication product through a single pharmacy company directly to the patient with minimal pharmacist oversight.

ASHP staff is monitoring the impact of the recently launched collaboration between a drug product manufacturer and retail pharmacy/pharmacy benefit manager that provides mail distribution of sildenafil. This model, which allows patients to submit a prescription provided by their physician through an online portal, has similarities to specialty pharmacy distribution models, as noted in the background of the recommendation. This partnership is intended, in part, to prevent counterfeiting, but it also has the potential to alter the pharmacist-patient relationship. Staff will monitor the growth of this program and determine its impact on areas addressed in ASHP policy, including transitions of care (ASHP policy 1208), medication adherence (ASHP policy 1222) and medication reconciliation, as well as our support for activities related to patient counseling and education.

Distinctive Labeling of Standardized Drug Concentrations and Dosing Units (Recommendation): John Armitstead (FL)

That ASHP encourage manufacturers to include, and to advocate that the FDA require, distinctive labeling of standardized drug concentrations and dosing units to minimize the risk of medication errors.

The Council on Public Policy discussed the recommendation at its September meeting (see Other Council Activity). The Council concluded that the issue merits further consideration but felt that it did not have sufficient information to develop ASHP policy at this time. The Council will reconsider the issue at its next meeting.

Development of a Medication Safety Credential (Recommendation): Daniel Degnan, John Hertig (IN)

That ASHP partner with other organizations to develop a medication safety credential that deems a pharmacist an expert in the field of medication safety.

The idea of a medication safety credential was discussed by the Council on Education and Workforce Development in 2012. One of the recommendations from the Council in that discussion was that ASHP "continue to evaluate existing patient safety credentials to determine if there is alignment that might lead to ASHP endorsing, partnering, or collaborating with such organizations in the future." ASHP is actively evaluating the suitability and feasibility of such a credential with other partner organizations.

Glossary of Terms Used in ASHP Policy (Recommendation): Emily Alexander (TX)

That ASHP be responsible for the development of a glossary of terms for use in policy.

Many of the terms used in ASHP policy are currently defined, but only in other places (see examples below). The Board of Directors approved recommendation from the ASHP Task Force on Organizational Structure in September, which will lead to changes in the ASHP policy development process. The suggestion for a glossary will be considered as the Task Force recommendations are implemented.

<http://www.ashp.org/Import/PRACTICEANDPOLICY/HouseofDelegates/ASHPPolicyProcess.aspx>

<http://www.ashp.org/DocLibrary/BestPractices/BPIntro.aspx>

Standardization of Policy Nomenclature (Recommendation): Jamie Sinclair, John Pastor, Paul Wittmer (MN)

That ASHP standardize the use of "medication" in policy statements.

This recommendation is a good one, and standardization is something ASHP strives for as policies are created and revised. Terminology can vary, however, and often changes over time, leading to inconsistency in the language of ASHP policies and best practices. ASHP has occasionally updated the entirety of its policy language for consistency, and with plans to improve the policy development process (see, for example, the recommendation concerning a policy glossary), opportunities to make policy language more consistent will be identified and taken advantage of.

Expansion of Pharmacy Publications into the General Healthcare Executive Literature (Recommendation): Amanda Hansen (VA)

That ASHP develop strategies to publish appropriate pharmacy practice content describing the ability of pharmacists to positively impact patient care in general health care executive journals or similar media.

Over the years ASHP has strategically sought opportunities to foster publications in *AHA Hospitals & Health Networks*, American College of Healthcare Executive publications, and various other executive and decision-maker publications. ASHP has been successful in doing so in many instances, and has encouraged our members to seek opportunities to publish in state hospital organization journals and present at state meetings, and also take advantage of opportunities to publish and present nationally. ASHP provides tools and resources for members on our public relations resource center:

<http://www.ashp.org/menu/PracticePolicy/ResourceCenters/PublicRelations>

Revision of ASHP Minimum Standard to Include USP Chapter 1066 (Recommendation): Butch Habeger (TX)

That ASHP revise the ASHP Minimum Standard for Pharmacies in Hospitals to incorporate or reference to the USP General Chapter 1066, Physical Environments That Promote Safe Medication Use.

The latest edition of the *ASHP Minimum Standard for Pharmacies in Hospitals* was published in the September edition of *AJHP*, having been approved by the ASHP Board of Directors and in production when the recommendation was received. The revised minimum standard states the following:

Medication storage and preparation areas. There shall be suitable facilities to enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.(4)

4. American Society of Hospital Pharmacists. ASHP technical assistance bulletin on hospital drug distribution and control. *Am J Hosp Pharm*. 1980; 37:1097–103.

Although it would be premature to revise the Minimum Standard now, the recommendation will be retained so that when revised it includes a specific reference to Chapter 1066 along with reference 4. In the interim, when the referenced ASHP TAB is revised, it will include a reference to Chapter 1066 in the context of medication preparation and storage areas. In that way, Chapter 1066 would be incorporated by reference until the minimum standard is revised.

National Standardization of Oral Liquid Concentrations and Package Sizes (Recommendation): Kevin Marvin (SOPIT)

That ASHP advocate for the national standardization of oral liquid concentrations and package sizes.

The Council on Pharmacy Practice considered the recommendation and developed Policy Recommendation A.

Timely Drug Database Updates in EHRs (Recommendation): Kevin Marvin (SOPIT)

That ASHP advocate that medication, decision support, and formulary databases used to support electronic prescribing by physicians and other care providers be required to have timely updates.

ASHP policy 1302, Interoperability of Patient-Care Technologies, states: “To encourage the integration, consolidation, and harmonization of medication-related databases used in patient care technologies to reduce the risk that outdated, inaccurate, or conflicting data might be used...” This policy has been published in *ASHP’s Best Practices for Hospital and Health-System Pharmacy* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to participate in the Pharmacy HIT Collaborative, which is working to address the issue of data integrity and accuracy needed by health care practitioners in the medication use processes. The work of the Collaborative is supported by the Section of Pharmacy Informatics and Technology, which continues to provide practitioner expertise on advocacy to address this issue. To support members in the advancement of pharmacists’ roles affecting interoperability of patient-care technologies, ASHP has developed the Summer Meeting 2014 Informatics Institute and launched the Pharmacy Informatics Essentials distance learning programs.

Amendment of Policy on Standardization of IV Drug Concentrations (Recommendation): Nancy Korman (CA), Carol Rollins (AZ), Melinda Burnworth (AZ), Christi Jen (AZ), Christine Antczak (CA)

That the ASHP House of Delegates insert the following language as a third clause in ASHP policy 1306, Standardization of Intravenous Drug Concentrations: “To encourage pharmacists to implement standardized drug concentrations and dosing units in their individual organizations.”

The recommendation was considered by the Council on Pharmacy Practice at its September meeting. The Council concluded that the House-approved language permitted pharmacist implementation of standardized drug concentrations but also encouraged broader efforts, which the Council endorsed. The Council also recommended a policy on standardization of oral liquid medication concentrations.

Wellness Activities at ASHP Meetings (Recommendation): Meghan Swarhout (MD)

That ASHP incorporate more health and wellness activities into meetings to promote healthy living for members while attending ASHP meeting.

ASHP understands the importance of promoting healthy living at our meetings and in the daily lives of members, patients, and staff. ASHP will explore the potential viability of incorporating health and wellness activities into future meetings, keeping the meeting purpose and scheduling priorities in mind.

Update of ASHP Policy 1218, Approval of Biosimilar Medications (Recommendation): Thomas Kirschling (CO)

That ASHP address physician notification as a barrier to interchange of biosimilar products.

The Council on Public Policy considered this recommendation at its meeting in September and developed Policy Recommendation D.

ASHP Monitoring of Impact of New York I-STOP Legislation (Recommendation): Frank Sosnowski (NY)

That ASHP work closely with New York State Council of Health-System Pharmacists to monitor the New York I-STOP legislation and its impact on patient care and pharmacy workflow in relation to the choice or use of hydrocodone and hydrocodone combination products.

ASHP will to monitor the impact of changes that will be implemented under the Internet System for Tracking Overprescribing (I-STOP) Act. I-STOP, which is intended to improve how the state’s existing prescription drug monitoring program (PDMP) collects data and how and by whom that data is used, and may identify best practices for implementation in other states. In addition to this monitoring, ASHP welcomes the input of the New York Council of Health-System Pharmacists and individual pharmacists who practice in the state. ASHP will also continue to monitor other state-based activities to curb prescription drug abuse and the impact of NABP InterConnect, which provides a mechanism to share data among state-based PDMP.