



House of Delegates Session—2017

June 4 and 6, 2017
Minneapolis, Minnesota

Proceedings of the 69th annual session
of the ASHP House of Delegates,
June 4 and 6, 2017

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Paul W. Abramowitz, Secretary

The 69th annual session of the ASHP House of Delegates was held at the Minneapolis Convention Center, in Minneapolis, Minnesota, in conjunction with the 2017 Summer Meetings.

First meeting

The first meeting was convened at 1:00 p.m. Sunday, June 4, by Chair of the House of Delegates Amber J. Lucas. Chair Lucas introduced the persons seated at the head table: John A. Armitstead, Immediate Past President of ASHP and Vice Chair of the House of Delegates; Lisa S. Gersema, 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 Susan Eads Role, Parliamentarian.

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

The roll of official delegates was called. A quorum was present, including 206 delegates representing 49 states and the District of Columbia (no delegates from Hawaii or Puerto Rico), as well as the federal services, chairs of ASHP sections and forums, ASHP officers, members of the Board of Directors, and ASHP past presidents (see Appendix I for a complete roster of delegates).

Chair Lucas reminded delegates that the report of the 68th 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 68th House of Delegates session were received without objection.

Report of the Committee on Nominations. Chair Lucas called on Erin Fox for the report of the Committee on Nominations (Appendix II).^a Nominees were presented as follows:

President 2018–2019

Philip J. Schneider, Pharm.D., B.S., FASHP, Director of Pharmacy, Olathe Medical Center, Olathe, KS

Kelly M. Smith, Pharm.D., FASHP, FCCP, Associate Dean and Professor, University of Kentucky College of Pharmacy, Lexington, KY

Board of Directors, 2018–2021

Leigh A. Briscoe-Dwyer, Pharm.D., BCPS, FASHP, Vice President of Clinical Affairs, PharMEDium Services, LLC, Lake Forest, IL

Julie A. Groppi, Pharm.D., FASHP, National PBM Program Manager of Clinical Pharmacy Practice Policy and Standards, Department of Veterans Affairs Clinical Pharmacy Practice Office, Palm Beach Gardens, FL

Gloria P. Sachdev, Pharm.D., B.S. Pharm., FASHP, President and CEO, Employers' Forum of Indiana; Clinical Assistant Professor, Purdue College of Pharmacy; and Adjunct Assistant Professor, Indiana University School of Medicine, Carmel, IN

Paul C. Walker, Pharm.D., FASHP, Clinical Professor and Director of Experiential Education and Community Engagement, College of Pharmacy, and Manager, Department of Pharmacy, Michigan Medicine, University of Michigan, Ann Arbor, MI

A "Meet the Candidates" session to be held on Monday, June 5, was announced. Chair Lucas announced the candidates for the executive committees of the five sections of ASHP.

Report of the Committee on Resolutions. President Gersema presented the Report of the Committee on Resolutions (Appendix III). Debate and action on the Report took place at the second meeting of the House.

Policy committee reports. Chair Lucas outlined the process used to generate policy committee reports (Appendix IV). She announced that the recommended policies from each council would be introduced as a block. She 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 Lucas reminded delegates that policies not separated by dividing the question would be voted on en bloc before the House considered the separated items.

Chair Lucas 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.)

Lisa S. Gersema, Chair of the **Board of Directors**, presented the Joint Council Task Force Policy Recommendation.

1. Medical Aid in Dying

To affirm that a pharmacist’s decision to participate or decline to participate in medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To take a stance of studied neutrality on legislation that would permit medical aid in dying for competent, terminally ill patients.

This policy supersedes ASHP policy 9915.

Todd A. Karpinski, Board Liaison to the **Council on Education and Workforce Development**, presented the Council’s Policy Recommendations 1 through 3.

1. Workforce Diversity

To affirm that a diverse and inclusive workforce contributes to health equity and health outcomes; further,

To advocate for the development of a workforce whose background, perspectives, and experiences reflect the diverse patients for whom pharmacists provide care.

2. ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process

To encourage all educators of the pharmacy workforce to use ASHP statements, guidelines, and professional policies as an integral part of education and training.

This policy supersedes ASHP policy 0705.

3. Educational Program Resources for Affiliated State Societies

To discontinue ASHP policy 0215, which reads:

To assist ASHP-affiliated state societies with information about potential educational program resources.

Timothy R. Brown, Board Liaison to the **Council on Pharmacy Management**, presented the Council’s Policy Recommendations 1 through 5.

*1. Any Willing Provider Status for Pharmacists and Pharmacies

To refer back to the Council on Pharmacy Management for further study, which reads:

To advocate for federal and state legislation and regulations ~~that will grant supporting~~ any willing provider status to pharmacists and pharmacies and improve patient care access and continuity of care; further,

To support affiliated state societies in advocating that pharmacists and pharmacies be included in state any willing provider legislation or regulation; further,

To acknowledge that healthcare plans and payers may develop and use criteria to determine access to plans or networks; further,

To advocate for public transparency on the criteria used to determine payer participation and the impact the use of such criteria has on the quality, access, cost, and choice of health-care services provided to patients enrolled in such plans or networks; further,

To advocate that healthcare plans and payers be required to disclose to pharmacists and pharmacies applying to the plan the selection criteria used to select, retain, or exclude a pharmacist or pharmacy from the healthcare plan or payer, including the criteria used to make exclusion determinations.

*2. Pharmaceutical Distribution Systems

To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To advocate that distributors not be permitted to make availability of drug products contingent on how those drugs products are used.

To oppose manufacturers, distributors, and wholesalers making availability of drug products contingent on how those products are used.

This policy supersedes ASHP policy 1016.

***3. Mobile Health Tools, Clinical Apps, and Associated Devices**

To advocate that patients, physicians, pharmacists, and other healthcare professionals be involved in the selection, approval, and management of mobile health tools, clinical software applications (“clinical apps”), and associated devices used by clinicians and patients for patient care; further,

To foster development of tools and resources to assist pharmacists in designing and assessing processes to ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices; further, [MOVED FROM LAST CLAUSE WITH NO CHANGES]

To advocate that decisions regarding the selection, approval, and management of mobile health tools, clinical apps, and associated devices should further the goal of delivering safe and effective patient care and optimizing outcomes; further,

To advocate that mobile health tools, clinical apps, and associated devices that contain health information be interoperable and, if applicable, be structured to allow incorporation of health information into the patient’s electronic health record and other essential clinical systems to facilitate optimal health outcomes; further,

To advocate that pharmacists be included in regulatory and other evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management; further,

~~To foster development of tools and resources to assist pharmacists in designing and assessing processes to ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices. [MOVED TO SECOND CLAUSE WITH NO CHANGES]~~

***4. Controlled Substances Diversion Prevention**

To encourage healthcare organizations to develop controlled substances diversion prevention programs and policies that delineate the roles, responsibilities, and oversight of all personnel who have access to handle controlled substances to ensure compliance with applicable laws and scopes of practice; further,

To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and surveillance, auditing, and monitoring are conducted on an continuous ongoing basis to support a safe patient-care environment, protect co-workers, and discourage controlled substances diversion.

***5. Revenue Cycle Compliance and Management**

To encourage pharmacists to serve as leaders in the development and implementation of strategies to optimize medication-related revenue cycle compliance, which includes verification of prior authorization, patient portion of payment, billing, reimbursement, and financial documentation reimbursement; billing, finance, and prior authorization; for the healthcare enterprise; further,

To advocate for the development of consistent billing and reimbursement policies and practices by both government and private payers; further,

To advocate that information technology (IT) vendors enhance the capacity and capability of IT systems to support and facilitate medication-related purchasing, billing, and audit functions; further,

To investigate and publish best practices in medication-related revenue cycle compliance and management.

This policy supersedes ASHP policy 1205.

Jennifer M. Schultz, Board Liaison to the **Council on Pharmacy Practice**, presented the Council’s Policy Recommendations 1 through 4.

***1. Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use**

To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that regulators (e.g., the Food and Drug Administration) have the authority to impose requirements on pharmaceutical manufacturers to provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacists ~~essts~~ repackage those drug products to minimize the risk of exposure; further,

To advocate that hazardous drug products intended for home use be labeled to warn that special handling is required for safety; further,

To advocate that pharmacists provide education to patients and caregivers regarding safe handling and appropriate disposal of hazardous drug products intended for home use.

***2. Expiration Dating of Pharmaceutical Products**

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures to ~~allow~~ encourage pharmaceutical manufacturers to readily update expiration dates, for as long as possible while maintaining drug potency and safety, to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

This policy supersedes ASHP policy 9309.

3. Primary and Preventive Care

To discontinue ASHP policy 9407, which reads:

To support primary and preventive care roles for pharmacists in the provision of pharmaceutical care; further,

To collaborate with physician, nursing, and health-system administrator groups in pursuit of these goals.

4. Nondiscriminatory Pharmaceutical Care

To discontinue ASHP policy 9006, which reads:

To adopt the following positions in regard to nondiscriminatory pharmaceutical care:

- All patients have the right to privacy, respect, confidentiality, and high-quality pharmaceutical care.
- No patient should be refused pharmaceutical care or denied these rights based solely on diagnosis.
- Pharmacists must always act in the best interest of individual patients while not placing society as a whole at risk.

Ranee M. Runnebaum, Board Liaison to the **Council on Public Policy**, presented the Council's Policy Recommendations 1 through 7.

***1. Partial Filling of Schedule II Prescriptions**

To advocate that state legislatures and boards of pharmacy create consistent laws and rules ~~that discourage overprescribing by~~ to allowing partial filling of Schedule II drugs; further,

To advocate that public and private entities construct criteria for partial filling to minimize the additional ~~practice~~ burden on patients, pharmacists, and healthcare organizations; further,

To advocate that pharmacists educate prescribers and patients about options for filling prescriptions for Schedule II drugs, including the risks of overprescribing, while recognizing the patient or caregiver's rights to make their own care and management decisions.

2. Restricted Drug Distribution

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

This policy supersedes ASHP policy 0714.

***3. Collaborative Drug Therapy Management (retitled: Collaborative Practice)**

To pursue the development of federal and state laws and regulations that authorize ~~collaborative drug therapy management by~~ pharmacists as providers within collaborative practice; further,

To advocate expansion of federal and state laws and regulations that optimize pharmacists' ability to provide the full range of professional services within their scope of expertise; further,

To advocate for federal and state laws and regulations that would allow pharmacists to prescribe and transmit prescriptions electronically ~~under collaborative drug therapy management protocols~~; further,

To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication-related outcomes; further,

To support affiliated state societies in their pursuit of state-level regulations allowing collaborative practice collaborative drug therapy management authority for pharmacists.

This policy supersedes ASHP policy 1217.

***4. Greater Competition Among Generic and Biosimilar Manufacturers**

To ~~support~~ advocate for legislation and regulations that promote robust greater competition among authorized generic and biosimilar pharmaceutical manufacturers.

This policy supersedes ASHP policy 0222.

5. Drug Testing

To recognize the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

This policy supersedes ASHP policy 9103.

6. Codes on Solid Dosage Forms of Prescription Drug Products

To discontinue ASHP policy 8709, which reads:

To support efforts requiring manufacturers of solid dosage form prescription drug products to imprint a readily identifiable code indicating the manufacturer of the drug product and the product's ingredients; further,

To make information on translation of the codes readily available.

7. Intermediate Category of Drugs

To discontinue ASHP policy 0220, which reads:

To support, with appropriate changes in federal statutes and regulations, the establishment of an intermediate category of drug products that do not require a prescription but are available only from pharmacists and licensed healthcare professionals who are authorized to prescribe medications; further,

To base such support on the following facts:

1. Some drug products that are potential candidates for switching from prescription-only to nonprescription status raise concerns about patient safety as nonprescription products; these products could be better controlled, monitored, and evaluated by making them available only from pharmacists and licensed healthcare professionals who are authorized to prescribe medications; and
2. Pharmacists have the education, training, and expertise to help patients make appropriate therapeutic decisions associated with the use of such drug products.

Further,

To support that the regulatory system for this intermediate category of drug products contain the following features:

Drug products appropriate for this intermediate category would be identified through the advice of pharmacists, physicians, and other licensed health professionals who are authorized to prescribe medications, on the basis of the medical conditions to be treated and potential adverse effects (as indicated in FDA-approved labeling);

Pharmacists would be able to provide drugs in this intermediate category directly to patients without a prescription, on the basis of appropriate assessment and professional consultation;

Licensed health professionals who currently have prescribing authority would continue to have the ability to prescribe medications in this intermediate category; and

Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reporting would be collected to help determine a drug product's eventual movement to nonprescription status, return to prescription-only status, or continuation in the intermediate category.

Donald E. Letendre, Board Liaison to the **Council on Therapeutics**, presented the Council's Policy Recommendations 1 through 7.

***1. Therapeutic and Psychosocial Considerations of Transgender Patients**

To support medication and disease management of transgender patients as a part of care unique to this population; further,

To advocate that transgender patients have access to pharmacist care to ensure safe and effective medication use; further,

To promote research on, education about, and development and implementation of therapeutic and biopsychosocial best practices in the care of transgender patients; further,

To encourage structured documentation of both a patient's birth sex and self-identified gender in ~~the patient medical~~ electronic health records.

***2. Pharmacist's Leadership Role in Glycemic Control**

To advocate that pharmacists provide leadership in caring for patients receiving medications for management of blood glucose; further,

To advocate that pharmacists be a member of the interprofessional healthcare team that coordinates glycemic management programs; further,

To encourage pharmacists who participate in glycemic management to educate patients, caregivers, prescribers, and other members of the healthcare team about glycemic control medication uses, metrics, drug interactions, adverse effects, lifestyle modifications, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

***3. Drug Dosing in Diseases That Modify Pharmacokinetics or Pharmacodynamics (retitled: Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics)**

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions disease states; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record systemic documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions disease states; further,

To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.

***4. Clinical Significance of Extremes of Weight and Weight Changes (retitled: Clinical Significance of Accurate and Timely Height and Weight Measurements)**

To encourage pharmacists to participate in interprofessional efforts to ensure appropriate accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy ~~to patients who may fall outside normal weight parameters or experience clinically significant changes in weight in a short period of time~~; further,

To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes.

***5. Pain Management**

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 foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects; further,

To encourage the education of pharmacists, pharmacy students, and other healthcare providers regarding the principles of pain management and substance abuse that encourage holistic, supportive approaches and reduce stigma surrounding opioid-use disorders.

This policy supersedes ASHP policy 1106.

6. Clinical Investigations of Drugs Used in Elderly and Pediatric Patients

To advocate for increased enrollment and outcomes reporting of pediatric and geriatric patients in clinical trials of medications; further,

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric and geriatric patients to facilitate safe and effective dosing of medications in these patient populations.

This policy supersedes ASHP policy 0229.

7. Safe and Effective Therapeutic Use of Invertebrates

To recognize use of medical invertebrates as an alternative treatment in limited clinical circumstances; further,

To educate pharmacists, patients, and the public about the risks and benefits of medical invertebrates use and about best practices for use; further,

To advocate that pharmacy departments, in cooperation with other departments, provide oversight of medical invertebrates to assure appropriate formulary consideration and safe procurement, storage, control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, and disposal; further,

To encourage independent research and reporting on the therapeutic use of medical invertebrates.

***8. Drug Dosing in Extracorporeal Therapies**

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To collaborate with stakeholders in enhancing aggregation of data on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To encourage the education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing in extracorporeal therapies.

This policy supersedes ASHP policy 1606.

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

The meeting adjourned at 4:00 p.m.

Second meeting

The second and final meeting of the House of Delegates session convened on Tuesday, June 6, at 4:00 p.m. A quorum was present.

Report of the Committee on Resolutions. President Gersema again presented the Report of the Committee on Resolutions (Appendix III). Elizabeth Shlom (NY), one of the Resolution's submitters, moved that the Resolution be referred to the Council on Public Policy for further study. The motion was seconded and the delegates voted to refer the Resolution.

Report of President and Chair of the Board. President Gersema 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 VI).

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

Board of Directors duly considered matters. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 6 to "duly consider" the policies and proposed Bylaws change amended at the first meeting. Sixteen policy recommendations were amended by the House of Delegates. The Board agreed with amendments of 15 of the policies with minor editorial changes to four of the amended policies to increase their clarity or provide consistency with other ASHP policies. The Board recommended that Council on Pharmacy Management Policy Recommendation 1, Any Willing Provider Status for Pharmacists and Pharmacies, be referred with its amendments to the originating Council for further study.

New Business. Chair Lucas announced that, in accordance with Article 7 of the Bylaws, there was one item of New Business to be considered. Chair Lucas called on Ryan Roux (TX) to introduce the item of New Business, "Reduction of Waste from Single Dose Vials" (Appendix VIII). Following discussion, the item was approved for referral to the Council on Pharmacy Practice. It reads as follows:

Reduction of Waste from Single Dose Vials

Motion:

To recommend the following for consideration as policy or refer to council for discussion.

To recognize a significant amount of chemically/pharmacologically active medication is wasted from single-dose vials due to limited sterility information; further

To encourage the FDA, CDC, Centers for Medicare and Medicaid Services, and US Pharmacopeial Convention to reconcile their views on vial contents and vial sharing; further,

To encourage strategies to decrease waste from single-dose vials through development of multi-dose vial presentations for currently available single-dose vials, creation of new vial sizes with appropriate for average patient doses, dose standardization, and develop standards to allow drug vial optimization (DVO) using closed-system drug transfer devices (CSTDs) where sufficient peer-reviewed literature supports each device's safety and efficacy for this purpose.

Background:

Proposal of this policy for consideration is timely given recent language in an Omnibus bill passed in May directing CMS to study the safety, and quality concerns associated with discarded drugs that result from weight-based dosing of medicines contained in single dose vials.

Suggested Outcomes:

In 2016, Peter Bach, et al found that \$1.8 billion in direct drug costs were wasted annually in the US from the top 20 cancer drugs sold in single-dose vials. The proportion of leftover drug in single-dose vials varies between 1% and 33%, and the cost of this wasted drug is often passed on to the patient, and if not, is absorbed by the health care system. Pharmaceutical manufacturers' profits are the direct beneficiary of this wasted medication and larger than necessary vial sizes. Several recent examples demonstrate continued movement by pharmaceutical manufacturers to decrease available vial sizes and increase profits. In February 2015, Merck discontinued a 50 mg presentation of pembrolizumab in the United States in favor of only a 100 mg presentation, while the 50 mg vial is still available in Europe. In May 2017, Genentech announced it would discontinue its 440 mg multi-dose vial of trastuzumab and replace it with a 150 mg SDV. The Merck change is estimated to produce \$1.2 billion in additional revenue over the next 5 years (on top of the \$1.2 billion in waste that was estimated from the 50 mg vial), and it is unknown at this time the additional revenue growth that will be generated for Genentech with its change.

In May 2017, the Hematology/Oncology Pharmacy Association (HOPA) hosted a Drug Wastage Summit and invited pharmaceutical manufacturers, CSTD manufacturers, and oncology pharmacists and practice leaders to discuss the issue of drug waste in oncology. During this Summit, several presentations were given showing the safety and efficacy of DVO by institutions, dose rounding programs, and efforts by one manufacturer to create vial sizes more appropriate for typical doses of a medication. At UNC, DVO has been practiced since 2011. It was estimated that their drug budget would be 93% higher (\$70.1 million vs. \$36.3 million) without the practice of DVO using a CSTD. Further, routine testing of vials used beyond 6 hours has shown safety of this practice in more than 1000 samples tested for microbiological contamination. In this setting, they have only found 2 positive samples, both during

the first month of testing and attributed to poor sampling technique, which represents a contamination rate of 0.2%. In the example of a drug manufacturer changing the vial size, a 190 mg vial size was added to the previously available 500 mg presentation. This additional size reduced waste by 87.6%

Supporting Policies: 1525, 1401, 0903, 0616

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

Recognition. Chair Lucas recognized members of the Board who were continuing in office (Appendix X). She 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 Lucas presented Immediate Past President Gersema with an inscribed gavel commemorating her term of office. Dr. Gersema recognized the service of Chair Lucas as Chair of the House of Delegates and a member of the Board of Directors.

Chair Lucas then installed the chairs of ASHP's sections and forums: Laura M. Traynor, Section of Ambulatory Care Practitioners; Kim W. Benner, Section of Clinical Specialists and Scientists; Linda M. Spooner, Section of Inpatient Care Practitioners; Joseph J. Lassiter, Section of Pharmacy Informatics and Technology; Jennifer E. Tryon, Section of Pharmacy Practice Managers; Calvin Ice, New Practitioners Forum; and Lauren Stanz, Pharmacy Student Forum. Chair Lucas then recognized the remaining members of the executive committees of sections and forums.

Installation. Chair Lucas then installed Paul W. Bush as President of ASHP, Stephen F. Eckel and Linda S. Tyler as members of the Board of Directors (Appendix X). (See Appendix XI for the Inaugural Address of the Incoming President.)

Adjournment. The 69th annual June meeting of the House of Delegates adjourned at 5:55 p.m.

^aThe Committee on Nominations consisted of Erin Fox, Chair (UT); Christene Jolowsky, Vice Chair (MN); Kimberly Benner (AL); John Pastor (MN); Linda Radke (KS); Davide Weetman (IA); and Lanita White (AR).

DELEGATES to the 2017 Session of the House

Appendix I

OFFICERS OF THE HOUSE

Amber Lucas, *Chair*
John Armitstead, *Vice Chair*
Paul Abramowitz, *Secretary*

OFFICERS AND BOARD OF DIRECTORS

Lisa Gersema, *President*
Paul Bush, *President-Elect*
John Armitstead, *Immediate Past President*
Amber Lucas, *Chair, House of Delegates*
Thomas Johnson, *Treasurer*
Paul Abramowitz, *Chief Executive Officer*
Jennifer Schultz, *Board Liaison, Council on Pharmacy Practice*
Todd Karpinski, *Board Liaison, Council on Education and Workforce Development*
Timothy Brown, *Board Liaison, Council on Pharmacy Management*
Ranee Runnebaum, *Board Liaison, Council on Public Policy*
Lea Eiland, *Board Liaison, Commission on Affiliate Relations*
Don Letendre, *Board Liaison, Council on Therapeutics*

PAST PRESIDENTS

Roger Anderson
Daniel Ashby
Jannet Carmichael
Kevin Colgan
Debra Devereaux
Diane Ginsburg
Mick Hunt
Marianne Ivey
Christene Jolowsky
Stan Kent
Herman Lazarus
Lynnae Mahaney
Kathryn Schultz
Philip Schneider
Bruce Scott
Steven Sheaffer
Thomas Thielke
Sara White
T. Mark Woods
David Zilz

STATE DELEGATES

Alabama (3)

Thomas Cobb
Brenda Denson
Pamela Stamm

Alaska (2)

Shawn Bowe
Lara Nichols

Arizona (3)

Melinda Burnworth
Carol Rollins

Arkansas (2)

Rayanne Story
Lanita White

California (8)

Christine Antczak
Victoria Ferraresi
Steve Gray
Brian Kawahara

Sarah McBane
Stacey Raff
Kethen So
Robert Stein¹
Martin Iyoya²

Colorado (3)

Ashley Espinosa
Michelle Hilaire
Karen McConnell

Connecticut (3)

David Goffman
Molly Leber
Stacy Vaeth

Delaware (2)

Michael Dejos

Florida (5)

Kathy Baldwin
Gary Dalin
Katelyn Dervay
Richard Montgomery
Risa Rahm²

Georgia (3)

Leslie Jagers
Jennifer Sterner-Allison
Christy Norman

Idaho (2)

Michael Dickens
Lindsay Hunt

Illinois (5)

Noelle Chapman
Travis Hunerdosse
Jennifer Phillips
Ed Rainville
Carrie Sincak

Indiana (3)

Amy Heck Sheehan
John Hertig
Tate Trujillo

Iowa (3)

Shane Madsen
Lisa Mascardo
David Weetman

Kansas (3)

Christopher Bell
Joan Kramer
Lindsay Massey

Kentucky (3)

Vylinda Howard
Catherine Shely
Rachel Swope

Louisiana (3)

Scott Dantonio
Monica Morgan
Jennifer Smith

Maine (2)

Chelsea Magee
Ellie Provisor

Maryland (4)

Stacy Dalpoas
Patricia Grunwald
Janet Lee
Asha Tata

Massachusetts (4)

Snehal Bhatt
Karl Gumpfer
Erin Taylor
Ross Thompson

Michigan (4)

Jesse Hogue
Nancy MacDonald¹
Lynette Moser²
Michael Ruffing
Paul Walker

Minnesota (4)

Melissa Carlson

Kevin Dillon
Kristi Gullickson²
Paul Krogh
Rachel Root¹

Mississippi (2)

Courtney Davis
Joshua Fleming

Missouri (3)

Joel Hennenfent
Amy Sipe
David Wolfrath

Montana (2)

Derek Burns
Amanda Patel

Nebraska (2)

Michele Faulkner
Jerome Wohleb

Nevada (2)

Adam Porath
Katherine Ward

New Hampshire (2)

Tonya Carlton
Robert Theirault

New Jersey (3)

Luigi Brunetti
Paul Goebell, III
William Herlihy

New Mexico (2)

Melanie Dodd
Juliann Horne

New York (5)

Leigh Briscoe-Dwyer
Christopher Jadoch¹
Joseph Pinto
Vickie Powell²
Elizabeth Shlom
Mark Sinnett

North Carolina (4)

Susan Bear
Robert Granko
Brian Marlow
Jacqueline Olin

North Dakota (2)

Maari Loy

Ohio (5)

Dale English, II
Mary Ellen Hethcox
Karen Kier
Chris Paxos
Mark Thomas

Oklahoma (3)

Ann Lloyd
Kari McCracken
Edna Patatanian

Oregon (3)

Sarah Deines
Zachary McCall
Daniel Rackham

Pennsylvania (5)

Nishaminy Kasbekar
Patricia Kienle
William O'Hara
Richard Pacitti
Jill Rebeck

Rhode Island (2)

Shannon Baker
Marco Delbove

South Carolina (3)

Lynn Etheridge
Joel Melroy
Natasha Nicol

South Dakota (2)

Erin Christensen
Thaddaus Hellwig

Tennessee (4)

Jeffrey Binkley
Kelly Bobo
Micah Cost²
Leah Ingram
Jodi Taylor¹

Texas (6)

Tammy Cohen
Diane Fox
Shane Greene
Sidney Phillips
Ryan Roux
Jeffrey Wagner

Utah (3)

Erin Fox
Elyse MacDonald
Krystal Moorman

Vermont (2)

Julie MacDougall
Jeffrey Schnoor

Virginia (4)

Scott Anderson
Lisa Hammond
Craig Kirkwood
Kelly Martin

Washington, D.C. (2)

Carla Cabanilla Darling
Laura Zandal

Washington State (4)

Cyndy Clegg
Rena Gosser
Steven Riddle
Roger Woolf

West Virginia (2)

Justin Hare
Jason Strow

Wisconsin (4)

Terry Audley
David Hager
Arlene Iglar
Justin Konkol

Wyoming (2)

Linda Gore-Martin

SECTIONS AND FORUMS

DELEGATES

Ambulatory Care Practitioners

Kristy Butler

Clinical Specialists and Scientists

Casey White

Inpatient Care Practitioners

Jennifer Robertson

Pharmacy Informatics and Technology

Sylvia Belford

Pharmacy Practice Managers

Rick Couldry

New Practitioners Forum

Calvin Ice

Pharmacy Student Forum

Lauren Stanz

FRATERNAL DELEGATES

US Air Force

Winnie Lok-Park

US Army

Gwendolyn Thompson²

US Navy

Alice Moss

US Public Health Sve

Ashley Schaber

Veterans Affairs

Julie Groppi

¹Sat in Sunday House Meeting only

²Sat in Tuesday House Meeting only

House of Delegates

HOUSE OF DELEGATES

REPORT OF THE

COMMITTEE ON NOMINATIONS

June 4, 2017

Minneapolis, Minnesota

Erin Fox (Chair), Utah
Christene Jolowsky (Vice Chair), Minnesota
Kimberley Benner, Alabama
John Pastor, Minnesota
Linda Radke, Kansas
David Weetman, Iowa
Lanita White, Arkansas
Meghan Swarthout (1st Alternate), Maryland
Steven Riddle (2nd Alternate), Washington
Noelle Chapman (3rd Alternate), Illinois
Kethen So (4th Alternate), California

ASHP COMMITTEE ON NOMINATIONS

Madam Chair, Fellow Delegates:

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

Selection of nominees for ASHP office involves a series of very challenging decisions on the part of the Committee. Ultimately, those decisions are intended to permit the membership to select leaders with the professional, intellectual, and personal qualities of leadership that will sustain the dynamism and pioneering spirit that have characterized both ASHP and its nearly 45,000 members who provide patient care service across the entire spectrum of care.

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

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

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

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

The Committee's year-long process of receiving nominations and screening candidates is designed to solicit extensive membership input and, ultimately, to permit the Committee to candidly and confidentially assess which candidates best fit ASHP's needs. The Committee has met twice in person since the last session of the House of Delegates: on December 6, 2016, at the Midyear Clinical Meeting in Las Vegas, Nevada; and on April 18, 2017, at ASHP headquarters; and met once via

teleconference. Review of nominees' materials was conducted continuously between March and April 2017 solely via secure electronic transmissions. This process has been reviewed for quality improvement and will be repeated for the 2017–2018 nomination cycle.

As in the past, the Committee used various means to canvass ASHP members and state affiliates for candidates who they felt were most qualified to lead us. All members were invited via announcements in ASHP News and Daily Briefing, social media, online ASHP NewsLink bulletins, and the ASHP website to submit nominations for the Committee's consideration. Nominations from affiliated state societies were solicited through special mailings and the "state affiliate" edition of the online NewsLink service. At the 2016 Midyear Clinical Meeting, the Chair and ASHP Chief Executive Officer made themselves available to receive nominations personally in a location and at a time that were publicized in ASHP news publications and correspondence.

Based upon recommendations from membership, state affiliates, and ASHP staff, the Committee contacted over 500 individuals identified as possible candidates. Some individuals were invited to accept consideration for more than one office. Of the nominees who responded to the invitation to place themselves in nomination, the breakdown by office is as follows:

PRESIDENT-ELECT: 8 accepted

BOARD OF DIRECTORS: 21 accepted

A list of candidates that were slated was provided to delegates following the Committee's meeting on April 18, 2017.

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

Philip J. Schneider, Pharm.D., B.S., FASHP (Olathe, KS)

Kelly M. Smith, Pharm.D., FASHP, FCCP (Lexington, KY)

Board of Directors

Leigh A. Briscoe-Dwyer, Pharm.D., BCPS, FASHP (Lake Forest, IL)

Julie A. Groppi, Pharm.D., FASHP (Palm Beach Gardens, FL)

Gloria P. Sachdev, Pharm.D., B.S.Pharm., FASHP (Carmel, IN)

Paul C. Walker, Pharm.D., FASHP (Ann Arbor, MI)

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

PRESIDENT-ELECT

PHILIP J. SCHNEIDER, Pharm.D., B.S., FASHP (phil.schneider@olathehealth.org) is Director of Pharmacy, Olathe Medical Center, Olathe, Kan. He earned his B.S. and Pharm.D. degrees from the University of Iowa and completed an internal medicine residency at the Medical University of South Carolina. In his 27 years with Olathe Health, he has led many programmatic and technological initiatives that have resulted in robust practice model expansion and optimal drug use.

Schneider has served ASHP in a variety of capacities, including Treasurer (2010-2016); Board of Directors (2004-2007); Chair, Council on Organizational Affairs; Committee on Nominations; and state delegate for many years. He is past Treasurer and Presidential Officer of the Kansas Society of Health-System Pharmacists. He received the Kansas Council of Health-System Pharmacy's Legacy Award, KSHP's Harold Godwin Award for Outstanding Achievement, and the Kansas Health-System Pharmacist of the Year. He has served as mentor to many pharmacy students and residents.

KELLY M. SMITH, Pharm.D., FASHP, FCCP (kelly.smith@uky.edu) is Associate Dean and Professor, University of Kentucky College of Pharmacy. A University of Georgia and UF Health Jacksonville residency program graduate, she began her career as a drug information pharmacist and board-certified pharmacotherapy specialist, was a long-time PGY1 program director, and developed Kentucky's statewide residency network. She focuses on projecting the profession's needs to shape workforce capacity, postgraduate training, and practice innovations.

Smith's ASHP service includes Board of Directors; Chair, Section of Clinical Specialists and Scientists; Chair, Commission on Credentialing; Council on Therapeutics; Council on Education and Workforce Development; Pharmacy Technician Accreditation Commission; House of Delegates; PPMI delegate; Task Force on Organizational Structure; Task Force on Science; and *AJHP* Editorial Board. Others include UHC/Vizient Executive Committee; Chair, ACCP Drug Information PRN and Residency Task Force; and Chair, AACP Deans' Task Force. She has received awards from ASHP, KSHP, KPhA, ACCP, and AACP.

BOARD OF DIRECTORS

LEIGH A. BRISCOE-DWYER, Pharm.D., BCPS, FASHP (lbriscoe@pharmedium.com) is Vice President of Clinical Affairs for PharMEDium Services, LLC, Lake Forest, Ill. Previously, she served as Chief Pharmacy and Medication Safety Officer for the NorthShore – LIJ Health System in Lake Success, N.Y.

The focus of her career has been ensuring the safe and appropriate use of medications, encouraging pharmacists to serve as leaders when pursuing medication safety initiatives, and advocating for the expansion of the role and visibility of the pharmacist in all areas of healthcare.

Briscoe-Dwyer earned her B.S.Pharm. from Albany College of Pharmacy and her Pharm.D. from St. John's University. She has served the profession as President of NYSHCP and as a member of the New York State Board of Pharmacy. Her contributions to ASHP include service in the House of Delegates, on the FASHP Recognition Committee and the Council on Public Policy, and as Chair of the Nominations Committee.

JULIE A. GROPPPI, Pharm.D., FASHP (Julie.groppi@va.gov) is the National PBM Program Manager of Clinical Pharmacy Practice Policy and Standards for the Department of Veterans Affairs Clinical Pharmacy Practice Office in Washington, D.C. She is responsible for the development and implementation of clinical pharmacy practice policy, resources, and programs that optimize and highlight the advanced practice role of pharmacist providers.

Groppi earned her Pharm.D. degree from Mercer University and completed an ASHP-accredited residency in Gainesville, Fla. For over 19 years, Groppi has worked in a variety of clinical pharmacy and leadership roles throughout the Department of Veterans Affairs within the state of Florida.

Groppi has served ASHP in a variety of ways, including as Chair and Vice Chair of the Council on Pharmacy Practice, Clinical Leadership SAG for Credentialing and Privileging, Competency Assessment team, as well as delegate in the House of Delegates.

GLORIA P. SACHDEV, Pharm.D., B.S.Pharm., FASHP (gsachdev@purdue.edu) serves as President and CEO of the Employers' Forum of Indiana; Clinical Assistant Professor, Purdue College of Pharmacy; and Adjunct Assistant Professor, Indiana University School of Medicine. Gloria earned her B.S. and Pharm.D. from the University of Oklahoma, completing a primary care residency at the VA in Madison, Wis. She managed patients under collaborative practice for 12 years and has consulted for pharmacists, health systems, and colleges nationally to develop financially sustainable ambulatory care services. Since 2013, she's provided 28 invited national presentations, eight at ASHP conferences.

ASHP endeavors include Vice Chair/Chair, Section of Ambulatory Care Practitioners (SACP) Compensation and Practice Sustainability SAG; Director-at-Large, SACP Executive Committee; and Vice Chair/Chair, Council on Public Policy. Sachdev is currently Director-at-Large for the Indiana state affiliate. In 2016, she received ASHP's Distinguished Service Award for Ambulatory Care and Pharmacist of the Year from Indiana's pharmacist association.

BOARD OF DIRECTORS (continued)

PAUL C. WALKER, Pharm.D., FASHP (pcwalker@umich.edu) is Clinical Professor and Director of Experiential Education and Community Engagement, College of Pharmacy, and Manager, Department of Pharmacy, Michigan Medicine, at the University of Michigan, Ann Arbor. He previously served in clinical practice and leadership roles at the Detroit Medical Center and Henry Ford Health System and held faculty appointments at Wayne State University.

Walker received his B.S.Pharm. and Pharm.D. from Wayne State University. He completed an ASHP-accredited residency at Children's Hospital of Michigan and a residency in pediatric pharmacy practice at the University of Tennessee.

His ASHP service includes Chair, Committee on Nominations; Commission on Affiliate Relations; ASHP Foundation Donor Retention Subcommittee; Michigan delegate; and poster abstract reviewer for the Summer and Midyear Clinical Meetings. He served as a board member of the Michigan Society of Health-System Pharmacists and the Michigan Pharmacists Association, and has received awards from both associations.

House of Delegates

REPORT OF THE COMMITTEE ON RESOLUTIONS

June 3, 2017

Minneapolis, Minnesota

Lisa M. Gersema, Chair
Paul W. Bush, Vice Chair
John A. Armitstead
Timothy R. Brown
Lea S. Eiland
Thomas J. Johnson
Todd A. Karpinski
Donald E. Letendre
Amber J. Lucas
Ranee M. Runnebaum
Jennifer M. Schultz
Paul W. Abramowitz, Chief Executive Officer

Article 7.2.2.1 of the ASHP Rules of Procedure for the House of Delegates states:

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.

Pursuant to the above article, the Committee on Resolutions presents the attached resolution to the House of Delegates. The recommendation of the Committee is to **not adopt the resolution**. Although the Committee supports the resolution's intent, a recommendation to not adopt was made because the Committee concluded that Council on Public Policy Recommendation 2, Restricted Drug Distribution, was a better means to achieve the outcome sought in the resolution. The Council's policy recommendation reads:

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

The Committee noted that the policy recommendation, approved by the Board of Directors in January and currently before the House, opposes "restricted drug distribution systems...created for any reason other than patient safety." The resolution does not recommend any restrictions on the criteria to be developed by the Food and Drug Administration (FDA) for defining specialty drug products. The Committee agreed with the Council's reasoning that restricted drug distribution systems may be justified as a means to improve patient safety by encouraging close monitoring of patients using especially dangerous drugs. The Committee further noted that the FDA currently has the authority to establish Risk Evaluation and Mitigation Strategies (REMS), which the policy recommendation envisions as the sole means FDA would have to establish a restricted drug distribution system, and that FDA only has authority over restricted distribution systems within the REMS program. The Committee felt it was not in the best interest of patients and providers to extend FDA authority over restricted distribution systems beyond the REMS program. The Committee concluded that the Council's policy recommendation was a better means to achieve the outcome sought in the resolution (to empower ASHP "to advocate for tightened control on specialty drug products that are only available through specialty pharmacies and a restricted drug distribution system") and that it should therefore recommend against adoption of the resolution.

Delegates are reminded that they are voting on the substance of the resolution, which is approval of the motion "To advocate that the Food and Drug Administration establish criteria for categorizing specialty drug products that will only be available through a restricted drug distribution system." The options for House action on the resolution, to be taken at the second meeting, are to (a) approve the

motion; (b) defeat the motion **(the option recommended by the Committee on Resolutions)**; (c) refer the motion for further study by a committee or task force to be determined by the Board of Directors; or (d) amend the resolution, which would then require due consideration by the Board of Directors at its next meeting in September.

Resolution for 2017 ASHP House of Delegates: FDA Criteria for Specialty Drug Products Available through Restricted Drug Distribution**Submitted By:**

Elizabeth Shlom
21 Lookout Place
Ardsley, NY 10502
212-506-5448
shlom@gnyha.org

Joseph Pinto
22-27 80th Street
East Elmhurst, NY 11370
845-721-5561
rxrx864@aol.com

Subject: FDA Criteria for Drug Products Available through Restricted Drug Distribution

Received: March 3, 2017

Motion:

To advocate that the Food and Drug Administration establish criteria for categorizing specialty drug products that will only be available through a restricted drug distribution system.

Background:

Specialty medications are only available through limited distribution channels and provide a unique challenge to health-system pharmacy. Although only about 1% of all prescriptions today are for specialty medications, their cost is much higher than traditional medications. By 2020 it is expected that specialty medications will make up nearly half of the expenditures of all medications sold.^{1,2} Currently, the pharmaceutical manufacturer determines when a drug product will only be made available through a specialty pharmacy or restricted drug distribution channels. In most cases, specialty medications are for a niche patient population and require safety measures, patient education, and monitoring that go above and beyond what a traditional community pharmacy can provide. When a patient receiving a specialty medication is admitted to a hospital, the hospital is unable to order the medication from the specialty pharmacy, but instead relies on the patient to bring the medication to the hospital with them.

Limiting the availability of medications through specialty distribution channels provides a number of challenges to the health-system pharmacy. First, when a patient brings his or her own medication to the hospital, the chain of custody for the medication is unavailable to the health-system pharmacy and the pharmacy department is unable to verify the integrity of the drug product. Second, if the medication is to be administered by the health-system care providers, an administration fee can be charged but the health-system must be careful not to charge the patient for the medication itself since the patient has already paid for it. Third, if the health-system care provider wants to initiate a specialty medication while a patient is in the hospital, the complicated process for ordering and receiving the specialty medication is likely to result in a delay in therapy if it is even possible for the

pharmacy department to order and receive the medication. Finally, although it is possible for health systems to establish their own specialty pharmacies, this is a labor- and cost-intensive process and doesn't guarantee that the institution will be provided access to all specialty medications that their patients may need.

The number of specialty medications is growing at a projected rate of 20% per year. Some health systems refuse to allow patients to bring specialty drug products into the hospital because of the challenges in managing and administering a medication that did not go through the usual supply chain process. But this can jeopardize patient care. Pharmaceutical manufacturers currently determine, based on their own criteria, whether a new medication will be considered a specialty drug product and what distribution channels will be used. The Food and Drug Administration (FDA) does not have an official definition or designation for this class of drugs. The cost of specialty drugs is generally much higher than traditional medications – as high as \$750,000 per year, with the specialty pharmacy handling often considered one of the reasons justifying the high cost.³ Despite the lack of a consistent definition of a specialty drug product, insurers have a number of strategies in which they attempt to limit use of these expensive medications, such as using a specialty drug cost tier, limiting patients to receiving a 30-day supply after a first fill limit of 1-2 weeks, requiring prior authorization, among others.⁴ By developing FDA criteria for when a drug product would only be available through specialty pharmacies and a restricted drug distribution system, the number of drugs in this category could be minimized and there would be assurance that only the most critical medications would be included.

References

1. Edlin M. Top pharmacy challenges of 2017. *Managed Healthcare Executive*. 2017;27(1):23-25.
2. Our 2020 Outlook for Specialty Pharmacy Revenues. 2016, April 21. Retrieved from <http://www.drugchannels.net/2016/04/our-2020-outlook-for-specialty-pharmacy.html>
3. Herrick DM. Specialty drugs and pharmacies. National Center for Policy Analysis. Policy Report No. 355. 2014, May 22. Retrieved from <http://www.ncpa.org/pdfs/st355.pdf>
4. Kirchhoff SM. Specialty drugs: background and policy concerns. 2015, August 3. Retrieved from <https://fas.org/sgp/crs/misc/R44132.pdf>

Outcome: ASHP to advocate for tightened control on specialty drug products that are only available through specialty pharmacies and a restricted drug distribution system.



House of Delegates

Board of Directors Report on Policy Recommendations from ASHP Councils

as of April 11, 2017

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COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATIONS

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

Todd A. Karpinski, *Board Liaison*

Council Members

Meghan D. Swarthout, *Chair* (Maryland)
Nicole Clark, *Vice Chair* (Massachusetts)
Sophia Chhay, *New Practitioner* (Maryland)
Seena Haines (Mississippi)
Thaddaus Hellwig (South Dakota)
Patricia Knowles (Georgia)
Dena Lehmann, *Student* (Pennsylvania)
Neil MacKinnon (Ohio)
Krystal Moorman (Utah)
Kristine Parbuoni (California)
Mark Sinnett (New York)
Lanita S. White (Arkansas)
Erika Thomas, *Secretary* (Maryland)

1. Workforce Diversity

- 1 To affirm that a diverse and inclusive workforce contributes to health equity and
- 2 health outcomes; further,
- 3 To advocate for the development of a workforce whose background, perspectives,
- 4 and experiences reflect the diverse patients for whom pharmacists provide care.

Rationale

As the U.S. becomes more heterogeneous, the pharmacy workforce should reflect and respond to this increasingly diverse patient base. An inclusive pharmacy workforce is best able to positively impact the health and wellness of patients for whom pharmacists provide care. According to the Institute of Medicine, increasing diversity among healthcare 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.^{1,2} Diversity in the pharmacy workforce includes, but is not limited to, the categories of sexual orientation and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion, and persons with disabilities.³ A diverse pharmacy workforce will provide the best care for all patients.

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 Cohen JJ, Gabriel, BA, Terrell C. The case for diversity in the health care workforce. *Health Aff.* 2002;21(5):90-102.

³ American Medical Association. AMA policies on LGBT issues. <http://www.ama-assn.org/ama/pub/about->

Background

A 2015 House of Delegates recommendation urged the Council to consider a policy to promote, support, and advocate for developing a diverse workforce and addressing gaps in healthcare including, but not limited to, race and ethnicity as well as other gaps, such as socioeconomic and literacy gaps. The 2015 Council reviewed related ASHP policies 1414 and 0510 and decided to recommend amending policy 1414. The Council felt it important to note that the [ASHP Statement on Racial and Ethnic Disparities in Health Care](#) complements the ASHP policy positions, so all three must be considered when determining whether new or revised policy is needed. The 2016 House of Delegates voted to strike the final clause of policy 1414, “To advocate for an ethnically and culturally diverse workforce,” with an accompanying recommendation that the Council on Education and Workforce Development craft a separate policy on cultural and ethnic diversity of the workforce. The ASHP Board concurred with this decision. Additionally, there was a recommendation at the 2016 House of Delegates to expand the statement to be more inclusive by including sexual orientation and gender expression in the policy to better reflect workforce and patient-care needs.

2. ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process

- 1 To encourage all educators of the pharmacy workforce to use ASHP statements,
- 2 guidelines, and professional policies as an integral part of education and training.

(Note: This policy would supersede ASHP policy 0705.)

Rationale

ASHP members create professional policy that reflect best practices and influence the future direction of the profession and patient care. ASHP's professional policies contain varying levels of detail, but all contain guiding principles for the profession. The use of professional policy should be incorporated into all forms of professional education, including pharmacy and technician students, residents, and practitioners and widely used across the pharmacy profession.

Background

The Council voted to recommend amending ASHP policy 0705, ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To encourage all educators of the pharmacy workforce ~~faculties in colleges of pharmacy~~ and preceptors of ASHP-accredited residency training programs to use ASHP statements, guidelines, and professional policies as an integral part of education and training programs and courses.

ama/our-people/member-groups-sections/glb-t-advisory-committee/ama-policy-regarding-sexual-orientation.page
(accessed 2016 Oct 4).

The Council agreed that the use of ASHP statements, guidelines, and professional policies should not be limited to pharmacy college faculty alone, and that all ASHP guidance documents should be used widely across the entire pharmacy profession, including, but not limited to, residency training programs and pharmacy technician training and education programs.

3. Educational Program Resources for Affiliated State Societies

To discontinue ASHP policy 0215, which reads:

- 1 To assist ASHP-affiliated state societies with information about potential educational
- 2 program resources.

Background

The Council agreed that this process has been incorporated into routine ASHP practice and is no longer needed as a policy position. ASHP provides an array of large and small-scale educational programming for affiliates, including: the provision of Board and staff speakers on topics of national, professional and member interest; monthly live and recorded webinars on topics of professional interest; sessions on critical topics at both the Summer and Midyear Clinical Meetings; monthly newlinks; links on dedicated Connect pages for affiliates and other programming as suggested by state affiliates. Additionally, ASHP continues to work with a variety of programming providers to continue to evaluate and potentially add educational program resources for use by state affiliates, including actual live and recorded programming, platforms for use in recording and storing programming and identifying/evaluating potential program partners.

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.)

- Career Counseling (8507)
- Requirement for Residency (0701)
- Residency Programs (0704)
- Preceptor Skills and Abilities (1201)
- Qualifications and Competencies Required to Prescribe Medications (1202)
- Qualifications of Pharmacy Technicians in Advanced Roles (1203)

Other Council Activity

House of Delegates New Business Item: Impact of Intern Hours Changes Required For Licensure

Council members discussed the new business item that was presented to the 2016 House of Delegates related to recent California Board of Pharmacy action that eliminated the requirement for non-academic internship hours to permit out-of-state applicants to take the California State Licensure Examination. The Council addressed the question of whether internship hours acquired outside of introductory and advanced pharmacy practice experiences (IPPE/APPE) rotations are necessary and how much they contribute to new practitioner readiness. Council members felt that current ASHP policy 1110, Pharmacy Internships, is relevant and appropriate.

2014 Workforce Survey

The [2014 National Pharmacist Workforce Survey](#) provides an update on the pharmacy workforce and compares results to the last survey in 2009. The primary purpose of the survey is to collect reliable information on demographic characteristics, work contributions, and quality of work-life of the pharmacist workforce in the United States. Results of the survey allow analyses and trends in pharmacy workforce issues. The survey is conducted on an approximately four- to five-year cycle. The Council reviewed the most recent survey and noted the following developments:

- The proportion of women in the workforce continues to increase.
- Job satisfaction and career commitment is high.
- Pharmacists with a Doctor of Pharmacy degree rose significantly since 2009.
- Increasing job stress may be contributing to decreased job satisfaction.

- Those most satisfied with their job work outside of direct patient care.
- Pharmacists in chain settings work the longest hours.
- Time spent in patient-care services not associated with medications has increased since 2009.

Overall, the Council felt the workforce report included positive information for the profession. The Council recommended that ASHP support strategies to reduce workplace-related stress such as developing web-based or other educational resources, supporting ongoing research, and showcasing proven stress-reducing models.

Final Report on Pharmacy Technician Workforce Survey

The Council discussed results of the 2015 [Pharmacy Technician Workforce Survey](#). Council members noted that roles for pharmacy technicians are emerging in automation, inventory, procurement, patient safety, and quality assurance. The Council noted that the survey indicated that pharmacy technician survey participants reported feeling threatened by technology, undervalued in the workplace, and inadequately trained. It was also noted that survey participants were highly satisfied with pharmacist co-workers and rated job satisfaction highly. The Council agreed that ASHP should continue to develop more resources for technicians and technician education. The Council was advised that a consensus conference of pharmacy technician stakeholders will be held in February 2017. One objective of this conference is to develop consensus in the area of defining the entry-level (“generalist”) pharmacy technician. The Council also recommended that ASHP explore opportunities to conduct a pharmacy technician workforce survey specifically for technicians who work in health systems.

Technician Workforce: Meeting 2020 Goal

The Council discussion focused on updates and new educational opportunities that will assist in meeting the Pharmacy Technician Certification Board (PTCB) goal of requiring that initial candidates for certification complete a pharmacy technician education program accredited by the American Society of Health-System Pharmacists and the Accreditation Council for Pharmacy Education by the year 2020. The purpose of this goal is to advance pharmacy technician qualifications by elevating PTCB’s standards for national certification and recertification. The Council received an overview of the status of PTCB 2020 Initiative and discussed new educational models such as the newly accredited distance-learning program. The Council urged ASHP to continue to share information with members on advanced technician roles. The Council also encouraged continued communication with ASHP state affiliates on how to work with boards of pharmacy to require technician certification. Finally, Council members encouraged support for PTCB to expand specialty certification for advanced roles.

Residency Program Accreditation: Meeting 2020 Goal

The Council discussed progress on the ASHP goal that by 2020 completion of an ASHP-accredited postgraduate year one (PGY1) residency should be required for entry into practice for pharmacists who will be providing direct patient care. Council members agreed that

significant progress has been made in closing the gap between the number of available residency programs and the number of pharmacy graduates seeking residencies. The Council was also updated on advocating for reinstatement of CMS funding for PGY2 residencies.

The Council determined that existing ASHP policies are appropriate, robust, and supportive of the residency program accreditation goal. The Council encouraged ASHP to develop and market materials that support hospitals wishing to develop residency programs that do not have a teaching mission, including information on how to justify resident position to the C-suite. Finally, ASHP was encouraged to provide education on layered learning practice models.

Provider Status Readiness

The Council discussed readiness of the profession and ASHP members for passage of H.R. 592/S. 314, the Pharmacy and Medically Underserved Areas Enhancement Act (the Act). Member readiness needs for becoming providers in the Social Security Act were addressed. The Council recognized ASHP for providing robust education on advocating for provider status. Council members felt that pharmacy departments would be viewed differently by the C-suite after passage of this legislation—no longer as an expense, but as a provider. The need to educate the C-suite on new roles for pharmacists was discussed.

The Council felt that current ASHP policy adequately address policy needs for provider status readiness. The Council suggested developing educational resources for ASHP members, including educational tools on coding and billing as well as practical skills development education on providing direct patient care. The Council agreed that developing readiness packages for ASHP state affiliates to work with state boards of pharmacy executives to lead practice act and scope of practice changes would be valuable. The need to collect baseline data on current pharmacist-provided patient-care activities to assess the impact of provider status in underserved communities was discussed, and the Council recommended that ASHP work with other members of the [Patient Access to Pharmacists' Care Coalition](#) to explore this type of data collection. The Council also suggested that college of pharmacy faculty and pharmacy students will also need to be educated on new patient-care responsibilities and techniques as well as billing and coding.

Intercouncil Task Force on ASHP Policy on Formulary and Pharmacy and Therapeutics Management

The Council was informed that the goal of this Task Force is to assure consistency between all formulary and pharmacy and therapeutics management policies and assure that these policies are updated.

Student Debt

Tuition at colleges of pharmacy continues to rise, as does the debt of students graduating with Doctor of Pharmacy degrees. The majority of students, 87.7%, have borrowed money to finance education, while only 12.5% did not. The American Association of Colleges of Pharmacy

(AACCP) conducts an annual survey of graduating students. According to the 2016 National Summary Report, the average amount borrowed to finance pharmacy education for both public and private institutions was \$150,000, down from \$157,425 in 2015.

The Council noted several concerns about rising level of pharmacy student debt including that debt repayment may deter those interested in pursuing residencies and reduce the pool of potential pharmacy students.

The Council concluded that ASHP policy on the topic was not warranted at this time but offered suggestions for action on the topic. Council members identified many online resources available to students and suggested collecting them into a resource. Residents could be directed to this resource by residency program directors.

Update on 2017 Technician Consensus Conference

The Council received an update on the proceedings of the 2017 Pharmacy Technician Stakeholder Consensus Conference which focused on developing consensus across the profession on the knowledge, skills, and abilities required for entry-level pharmacy technicians. Conference participants generally agreed on the need for accredited training and certification. Conferees also agreed on a set of recommendations and plan to meet in the future to discuss how to implement these recommendations. Conference proceedings will be shared at a future meeting of the Council. The Council will examine ASHP policy at that time.

COUNCIL ON PHARMACY MANAGEMENT

POLICY RECOMMENDATIONS

The Council on Pharmacy Management is concerned with ASHP professional policies related to the leadership and management of pharmacy practice. Within the Council's purview are (1) development and deployment of resources, (2) fostering 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.

Timothy R. Brown, *Board Liaison*

Council Members

Roger A. Woolf, *Chair*
Tricia Meyer, *Vice Chair* (Texas)
Maxwell Anderegg, *Student* (Iowa)
Nitish Bangalore (Wisconsin)
Bradley Cagle, *New Practitioner* (Tennessee)
W. Lynn Ethridge (South Carolina)
Kenneth Jozefczyk (Georgia)
Christine Marchese (Rhode Island)
Katherine Miller (Illinois)
Robert S. Oakley (Kentucky)
Richard Pacitti (Pennsylvania)
Cynthia Williams (Virginia)
David Chen, *Secretary* (Maryland)

1. Any Willing Provider Status for Pharmacists and Pharmacies

- 1 To advocate for federal and state legislation and regulations that will grant any
- 2 willing provider status to pharmacists and pharmacies and improve patient care
- 3 access and continuity of care; further,
- 4 To support affiliated state societies in advocating that pharmacists and pharmacies
- 5 be included in state any willing provider legislation or regulation.

Rationale

Historically, any willing provider statutes have primarily been a concern for pharmacists in the traditional retail or community pharmacy practice settings, but as hospitals and healthcare organizations have become more engaged in developing ambulatory care service lines, pharmacists working in those settings increasingly find themselves excluded from payer networks. As pharmacists obtain provider status in a number of states, they recognize the infrastructure required to implement direct, independent patient care and billing for provider-based services. Including pharmacists and pharmacies as providers in any willing provider statutes will improve patient access to pharmacists' care by allowing pharmacists to access payer networks, assuming those pharmacists can fulfill the terms and conditions required by payers.

Background

The [National Conference of State Legislatures](#) (NCSL) describes any willing provider (AWP) statutes, sometimes referred to as any authorized provider statutes, as follows:

Any willing provider statutes are laws that require health insurance carriers to allow healthcare providers to become members of the carriers' networks of providers if certain conditions are met. Such statutes prohibit insurance carriers from limiting membership within their provider networks based upon geography or other characteristics, so long as a provider is willing and able to meet the conditions of network membership set by the carrier.

AWP laws can be broad in scope, applying to all or most licensed providers in the state. Broad laws typically either spell out a list of providers covered by the provisions (e.g., physicians, pharmacists, chiropractors, speech therapists, podiatrists, optometrists, facilities, etc.) or assert that the provisions apply to all providers licensed in the state without specifically listing any.

AWP laws can also be limited in scope. Frequently, the limited provisions apply to only pharmacies or pharmacists. In some cases, they apply to a limited number of allied professionals such as chiropractors, optometrists, psychologists, and social workers.

According to the NCSL, in late 2014 there were 27 states with AWP statutes. Although many of these laws have been in force for decades, the most recently enacted changes in AWP laws were passed in 2013, and in November 2014 South Dakota voters approved a broad AWP binding ballot question.

The Council reviewed ASHP policy on the impact of insurance design and manufacturers' decisions on patients' ability to obtain access to medications and pharmacy services. During this review the Council concluded it was necessary to review the impact of AWP laws and regulations on pharmacists' ability to care for patients and to offer provider-based services, both in the states where pharmacists have achieved provider status and in those where they have not. The Council discussed the three components that can be required to support access to patients and payers: a strong state scope of practice and/or collaborative practice act, a payer that recognizes pharmacists as providers, and the opportunity to meet payers' requirements to provide patient care services (i.e., AWP statutes).

2. Pharmaceutical Distribution Systems

- 1 To support drug distribution business models that meet the requirements of
- 2 hospitals and health systems with respect to availability and timely delivery of
- 3 products, minimizing short-term outages and long-term product shortages,
- 4 managing and responding to product recalls, fostering product-handling and
- 5 transaction efficiency, preserving the integrity of products as they move through the
- 6 supply chain, and maintaining affordable service costs; further,

- 7 To advocate that distributors not be permitted to make availability of drug products
- 8 contingent on how those drugs products are used.

(Note: This policy would supersede ASHP policy 1016.)

Rationale

Wholesaler and distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. Recently, some wholesalers have required that pharmacies ensure certain drugs are not used or sold for use for particular purposes, and there are concerns that this practice could grow. ASHP supports wholesaler and distribution business models that meet the requirements of hospitals and health systems, which includes the ability for pharmacies to obtain drug products for established patient care uses without restriction.

Background

The Council voted to recommend amending policy 1016, Pharmaceutical Distribution Systems, as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To support ~~wholesaler/~~drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To advocate that distributors not be permitted to make availability of drug products contingent on how those drugs products are used.

The Council discussed the 2016 ASHP House of Delegates recommendation describing the need for ASHP to consider the impact of mandated requirements by wholesalers for the purchasing pharmacy “to sign an agreement that they would not purchase for or resell certain agents to prisons because several pharmaceutical manufacturers were mandating this. If the agreement was not signed, the pharmacy would not be allowed to purchase these agents for their patients.” The concern was this requirement could set a dangerous precedent, with major implications on patient care for healthcare systems that do not agree with pharmaceutical company’s positions. This requirement is currently related to the European Commission’s [imposition of restrictions](#) on the export of anesthetics used in U.S. executions, which has the potential to exacerbate the already extreme drug shortages in the 34 states with the death penalty. In addition, the European Commission has added eight barbiturates to its list of restricted products on the grounds that they may be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment. Among the eight are

pentobarbital and sodium thiopental, the two drugs on which almost all U.S. executions depend.

The Council took into consideration ASHP's existing policy on capital punishment, recognizing the relationship between the 2016 ASHP House of Delegates recommendation and the ASHP policy. From this discussion the Council concluded there could be circumstances in which wholesalers or other drug distribution businesses might seek to restrict the use of drugs for established, evidenced-based patient care uses, which is not in the best interests of patients.

3. Mobile Health Tools, Clinical Apps, and Associated Devices

- 1 To advocate that patients, physicians, pharmacists, and other healthcare
- 2 professionals be involved in the selection, approval, and management of mobile
- 3 health tools, clinical software applications ("clinical apps"), and associated devices
- 4 used by clinicians and patients for patient care; further,

- 5 To advocate that decisions regarding the selection, approval, and management of
- 6 mobile health tools, clinical apps, and associated devices should further the goal of
- 7 delivering safe and effective patient care and optimizing outcomes; further,

- 8 To advocate that mobile health tools, clinical apps, and associated devices that
- 9 contain health information be interoperable and, if applicable, be structured to allow
- 10 incorporation of health information into the patient's electronic health record and
- 11 other essential clinical systems to facilitate optimal health outcomes; further,

- 12 To advocate that pharmacists be included in regulatory evaluation and approval of
- 13 mobile health tools, clinical apps, and associated devices that involve medications or
- 14 medication management; further,

- 15 To foster development of tools and resources to assist pharmacists in designing and
- 16 assessing processes to ensure safe, accurate, supported, and secure use of mobile
- 17 health tools, clinical apps, and associated devices.

Rationale

The use of mobile devices (e.g., smartphones, tablets) has become commonplace. Over 68% of adults own a smartphone, and 62% of those use their smartphones to access health information. In addition to these mobile devices, use of remote monitoring devices is also being rapidly integrated into healthcare. According to a 2015 survey, although only 16% of healthcare professionals currently use mobile health tools in caring for patients, 46% plan to do so in the next five years. With the proliferation of mobile health tools, clinical apps, and associated devices, healthcare organizations need to address the potential risks of application use. Particular concerns include (1) assessing the quality of mobile health tools, clinical apps, and

associated devices; (2) standardizing choices and use across the organization; and (3) ensuring the security of data and data storage.

To maximize the effectiveness of mobile health tools, clinical apps, and associated devices, they must be selected, approved, and managed with the goal of improving care and with input from representatives of all affected parties, including patients, physicians, pharmacists, and other healthcare professionals. In addition, their effectiveness is enhanced when they are interoperable (as described in ASHP policy 1302, Interoperability of Patient-Care Technologies) and the data stored within them can be incorporated into the patient's electronic health record and other essential clinical systems.

Providers and patients currently have little guidance regarding use of these resources or the management of the data they provide. The Food and Drug Administration and other regulatory agencies are just beginning to determine the scope of their oversight. As medication-use experts, pharmacists can contribute to the regulatory evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management. In addition, ASHP is committed to fostering development of resources to help pharmacists ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices.

Background

The Council discussed the growing development and use of mobile health tools, clinical apps, and associated devices. Many of these tools are specifically targeted to assisting individuals in their own health and wellness management. Patient engagement with these devices and apps can provide benefits such as greater adherence, reduced recall (memory) burden, and less manual entry of health information. The Food and Drug Administration (FDA) defines a "mobile medical app" as a software application that can be executed on a mobile platform (i.e., a handheld, commercial, off-the-shelf computing platform, with or without wireless connectivity) or a web-based software application that is tailored to a mobile platform but is executed on a server and meets the definition of device in section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), and is intended to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device.

The Council discussed cases and experiences with hospitals and health systems adopting use of mobile apps. One of the case studies discussed was Ochsner, which was the first hospital to integrate the Apple HealthKit with their Epic system, starting in 2014. Ochsner closely tracks, monitors, and reports on the very positive patient outcomes of their Integrated & Connected Health programs. Ochsner's OBar is a retail store that offers digital tablets loaded with vetted mobile apps to support consumer health and sells discounted devices (e.g., activity trackers, wireless scales, blood pressure cuffs, and glucometers). Other health systems, such as Carolinas HealthCare System, feature a combination of homegrown and commercial apps on its website for patients to access medical-related information. The UK's National Health Service announced that 20 mobile health (mHealth) apps and devices will be offered free of charge to patients and providers to boost innovation and patient engagement; this service is slated to begin in 2017.

The Council discussed potential issues with medical apps, including the similarity of those risks to those of traditional medical devices, and noted that certain mobile medical apps can pose potential risks to public health. The FDA intends to apply its regulatory oversight to

only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. The FDA believes that this subset of mobile medical apps poses the same or similar potential risks to the public health as currently regulated medical devices if they fail to function as intended. A combined 84 percent of mobile app users and mobile app executives believe that their mobile health apps are adequately secure, and 63% believe that app providers are doing everything they can to protect their mobile health apps. An astounding 98% of mobile apps tested lacked binary protection, and most consumers state they would change providers if they were aware of how insecure the mobile apps are. Additionally, the Council noted the large and growing number of apps that will not be covered by FDA oversight of medical devices and emphasized the importance of having pharmacists assume an important role in the selection and management of medication-related apps that may be suggested for patients' use or that patients may use on their own.

The ASHP Section of Pharmacy Informatics and Technology Executive Committee representative to Policy Week provided perspectives for the Council, mentioning the Section's interest in pursuing the development of education, resources, and a statement or publication for healthcare organizations to use when making decisions about the use of apps in patient care. In addition, the Section Executive Committee reviewed and endorsed the policy recommendation.

4. Controlled Substance Diversion Prevention

- 1 To encourage healthcare organizations to develop policies that delineate the roles,
- 2 responsibilities, and oversight of all personnel who handle controlled substances to
- 3 ensure compliance with applicable laws and scopes of practice; further,

- 4 To encourage healthcare organizations to ensure that all healthcare workers are
- 5 appropriately screened for substance abuse prior to initial employment and
- 6 monitored on a continuous basis to support a safe patient-care environment, protect
- 7 co-workers, and discourage controlled substances diversion.

Rationale

Abuse of controlled prescription drugs (CPDs) is on the rise in the U.S. According to the [2014 National Drug Threat Assessment Summary](#) from the Drug Enforcement Administration (DEA), deaths involving CPDs outnumber those involving heroin and cocaine combined. Additionally, the economic cost of nonmedical use of prescription opioids alone in the U.S. totals more than \$53 billion annually. All pharmacies and healthcare institutions that handle controlled substances are required to have storage and distribution systems in place to prevent diversion. Due to the numerous medication access points in most hospital distribution systems, diversion is sometimes difficult to detect. Theft of controlled substances by healthcare workers remains a serious problem that can lead to patient harm and jeopardize patient safety. Drug addiction among healthcare workers is well documented. [One survey](#) suggested that nurses who reported a perception of easier availability of controlled substances were almost twice as likely as others to divert and use a controlled substance. In [another survey](#) published in *AJHP*, 19% of

pharmacists reported use of a controlled substance without a prescription during the preceding 12 months. Even the most conservative estimates are that 8–12% of physicians will develop a substance abuse problem at some point during their career, although the exact rate of substance abuse among physicians is uncertain.

Pharmacy managers and pharmacists-in-charge have increasing responsibility for ensuring controlled substance management and storage across large healthcare organizations. This expanded responsibility has increased the risk to organizations as acquisitions of physician office practices, clinics, and other non-hospital-based business units continue. To ensure compliance with applicable laws and scopes of practice, ASHP advocates that healthcare organizations develop policies to describe the roles, responsibilities, and oversight of all personnel handling controlled substances throughout the organization. ASHP supports pre-employment screening and continuous monitoring of all healthcare workers to reduce the risk of controlled substances diversion.

Background

The Council considered this topic in response to a recommendation from the House of Delegates as well as staff recommendation. In 2015, the Council proposed new policy addressing controlled substance management and initiated work on guidelines to support improved controlled substance diversion prevention programs. During the development of the guidelines there continued to be a large number of publicized cases of controlled substance diversion in the U.S. These cases, along with gaps identified during the development of the guidelines, demonstrated the need for ASHP policy regarding organizational policy for managing employees who handle controlled substances.

5. Revenue Cycle Compliance and Management

- 1 To encourage pharmacists to serve as leaders in the development and
- 2 implementation of strategies to optimize medication-related revenue cycle
- 3 compliance, which includes verification of reimbursement, billing, finance, and prior
- 4 authorization, for the healthcare enterprise; further,

- 5 To advocate for the development of consistent billing and reimbursement policies
- 6 and practices by both government and private payers; further,

- 7 To advocate that information technology (IT) vendors enhance the capacity and
- 8 capability of IT systems to support and facilitate medication-related billing and audit
- 9 functions; further,

- 10 To investigate and publish best practices in medication-related revenue cycle
- 11 compliance and management.

(Note: This policy would supersede ASHP policy 1205.)

Rationale

Pharmacy has an increasingly important role in optimizing revenue capture and avoiding revenue erosion resulting from improper billing or inadequate documentation of medication-related charges. Pharmacy needs to be involved in aspects of medication-related billing, including not just pharmacy drug charges and billing but also contracting and negotiating for carve-outs. Pharmacy leaders need to actively engage senior leadership and collaborate with various departments to ensure organizational success in revenue cycle management.

Recently, organizations have experienced increasing compliance pressures. This pressure comes from many sectors, including Centers for Medicare & Medicaid Services (CMS) programs plus state-specific requirements, third-party payers, and financial intermediaries. These policies impact organizations in two ways: increased requirements before the insurers will pay for a claim, and increased audit pressure to be sure the organizations are billing accurately. The frequency and nature of audits has also been changing. Insurers have increased the use of audits to control costs. Government agencies have also increased the use of audits. CMS has implemented Recovery Audit Contractor (RAC) audits, and the Office of the Inspector General is also auditing organizations. Results of the audits can have significant financial impact on the organization when money needs to be returned based on improper billing or lack of documentation.

Historically, pharmacy departments have great strength in managing supply chain issues. Drug expenditures are typically a significant portion of any hospital's budget. Pharmacy is a key leader in managing these expenses. However, pharmacy departments are involved in broader revenue cycle management in variable ways. In some organizations, the billing or patient accounting departments handle all billing issues with various degrees of pharmacy involvement. Accurate billing requires integration of the organization's clinical services, pharmacy, billing, and charge master functions. The required elements for proper billing may reside in several systems. As coverage decisions become more complex, pharmacy expertise is increasingly required in the clinical coverage decisions and information integration in order to be successfully reimbursed for services. For the healthcare enterprise to successfully manage compliance and optimize revenue capture there must be effective collaboration among various departments. Pharmacy knowledge and leadership is increasingly required to ensure organizational success in revenue cycle management.

Each insurer has different requirements for coverage determinations, and coverage decisions have become more complex. More drugs now require prior authorization processes. In some cases, even if the prior authorization process has been used, the charge is denied. Medicare implemented the requirements for self-administered drugs (SADs) several years ago. Diabetic supplies are now handled under durable medical equipment (DME) requirements, which may require different data elements before a bill is processed. Medicaid requires the National Drug Code (NDC) prior to payment, and billing requirements for Medicare and Medicaid programs are not harmonized. Healthcare Common Procedure Coding System (HCPCS) codes also need to be attached where indicated. It is challenging to keep up with all the changes. New International Classification of Disease 10 (ICD-10) codes will further complicate required coding. Current IT solutions are inadequate and do not effectively facilitate effective billing. Current systems are often not designed to capture all necessary information required to properly document and bill. Even when necessary data is captured it often resides

in different departmental computer systems that are not integrated and designed to share data. There is a need for more effective IT solutions to facilitate both billing and audits. Greater consistency in billing and reimbursement practices would facilitate greater compliance and enable the development of effective technology solutions to facilitate the billing and reimbursement processes.

Since pharmacy leaders have had variable levels of engagement in revenue cycle management, there is a need for education, tools, and resources related to best practices. Some pharmacy departments have created a business manager position in part to deal with these issues. This position is often not a pharmacist, but a staff member with business education. New roles for pharmacy technicians have also emerged in this area. ASHP and the Section of Pharmacy Practice Managers (SPPM) should seek to develop and share best practices and provide education to support pharmacists in optimizing pharmacy's role in revenue cycle compliance.

Background

The Council voted to recommend amending ASHP policy 1205, Revenue Cycle Compliance and Management, as follows (underscore indicates new text):

To encourage pharmacists to serve as leaders in the development and implementation of strategies to optimize medication-related revenue cycle compliance, which includes verification of reimbursement, billing, finance, and prior authorization, for the healthcare enterprise; further,

To advocate for the development of consistent billing and reimbursement policies and practices by both government and private payers; further,

To advocate that information technology (IT) vendors enhance the capacity and capability of IT systems to support and facilitate medication-related billing and audit functions; further,

To investigate and publish best practices in medication-related revenue cycle compliance and management.

The Council discussed ASHP policies related to finance and management of the revenue cycle. The Council concluded that ASHP policies covered most critical elements but agreed that, given the increasing number of payer designs that do not include hospitals in network and the growing requirements for prior authorizations, it is important to include the need to verify reimbursement for medication therapies in managing the complete revenue cycle.

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.)

- Staffing for Safe and Effective Patient Care (0201)
- Performance Improvement (0202)
- Reimbursement for Unlabeled Uses of FDA-Approved Drug Products (0206)
- Standard Drug Administration Schedules (0707)
- Financial Management Skills (1207)
- Transitions of Care (1208)
- Value-Based Purchasing (1209)
- Pharmacist's Role in Health Care Information Systems (1211)

Other Council Activity

Formulary Management for Health Systems and Challenges Due to External Payers and Escalating Drug Prices

The Council voted to explore convening an interprofessional task force to assess the Principles of a Sound Drug Formulary System to ensure the principles described are current, based on the current healthcare environment.

The environment of formulary management impacting health-system pharmacy leaders has changed dramatically, which includes the influence of external payers, increasing drug prices, and the challenges of establishing formulary and drug policy decisions across multi-hospital systems and integrated delivery networks.

The "Principles of a Sound Drug Formulary System" was developed in collaboration with an interprofessional group of healthcare associations. The original document was approved in 2000 and affirmed in 2011. Over the past 30 years the maturation of prescription benefit management services, the introduction of Medicare Part D, changes in how group purchasing and industry contracting are handled, and the increasing costs of medications have resulted in the development of many formulary management systems across different sectors of healthcare and unique formularies among these sectors and associated payers. Additionally, even within health systems, as the accountability of patients across the continuum of care increases and selecting the most efficacious and economical medications (which may not be the best economic outcome for all practice sites of the health system) has begun to result in a new paradigm for formulary management decisions.

Controlled Substance Diversion and Patient Access

The Council voted to recommend that the Council on Public Policy amend ASHP policy 9103, Drug Testing, to read as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To recognize the use of pre-employment drug testing, random drug testing, or drug testing for cause during employment based on defined criteria and with appropriate validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that appropriate drug testing panels are utilized that have demonstrated effectiveness verifying presence of substances commonly abused and/or used illegally; further,

To advocate that in the event a healthcare worker tests positive to drug testing, then organization attempts to provide follow-up with infectious disease testing.

Controlled substance diversion and abuse has reached the attention at the highest levels in the U.S., with even the White House weighing in on the crisis. In the past 4-5 years, the DEA has levied large fines on chain drugstores, drug wholesalers, and, most recently, major hospitals. Pharmacy managers and pharmacists-in-charge have increasing responsibility of ensuring controlled substance management and storage across large healthcare organizations. The Council discussed the increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and the many challenges that exist for healthcare institutions in managing controlled substances.

The Council also discussed the recently completed [ASHP Guidelines on Preventing Diversion of Controlled Substances](#). During its development authors noted there was ASHP policy on what organizations should consider for pre-employment and for-cause drug testing but not for random drug testing, which is being considered by many healthcare organizations. To be in alignment with the recommendations of best practices in the newly developed guidelines the Council has recommended the proposed amendment.

The Council on Public Policy considered these suggestions and recommended amending policy 9103.

Formulary Management for Health Systems and ASHP Evaluation of Related Policies, Statements, and Guidelines

The Council voted to convene an intercouncil work group to conduct a thorough review of ASHP policies, statements, and guidelines related to pharmacy and therapeutics committees, formulary management, and drug policy development, with the purpose of ensuring ASHP

policies, statements, and guidelines reflect the current market environment and needs of ASHP members.

The Council discussed challenges facing health-system leaders, including:

- Pharmacy benefit managers dictating hospital formulary decisions (e.g., a hospital may have Brand A on the formulary, but a plan will not pay the provider unless they provide Brand B for both inpatient and outpatient prescriptions).
- Increasing pressure on pharmacy to hold the line on drug costs, which is quite challenging with the huge increases seen in the costs of brand and generic drugs, combined with the growth of the specialty drug market.
- Healthcare executives who may want simple solutions with unreasonable means for patient care, such as in one anecdote of a senior leader who was convinced that the path to cost savings was reducing the number of line items in the formulary, not looking at the utilization of the top 200 drugs that account for 80% of our total drug spend.
- Questions of ethics and patient access to expensive medications, drugs in short supply, and organizational budget discipline.
- Outpatient pharmacy charges and revenue optimization in a population health model.
- Specialty pharmacy and the impact of site-of-care decisions on which drugs are covered for patients.
- The challenge of determining whether certain chronic disease management drugs need to be or should be given during an inpatient admission.
- The impact on formulary decisions and cost management when drugs historically given in clinics may be administered in hospital, since the organization owns all the expense anyway and the inpatient setting may be felt to be best site of care.
- The need to reassess to role of pharmacy and therapeutics committees and the traditional membership of these committees.
- The impact of perpetual drug shortages on formulary management and patient safety.

The Council agreed that numerous challenges and environmental changes are making it increasingly difficult to manage budgets; the difficulty of ensuring hospital leadership understands the complexity of formulary management, the impact of payers, and the responsibility to patients require ASHP to assess its existing policies and resources for pharmacy leaders. The Council recommended that the key goals of an intercouncil workgroup would include a primary goal of establishing a sustainable formulary process to meet the needs of patients served across the continuum of healthcare organizations. Fundamental components would include:

- Effective data management that optimizes evidence, utilization, and cost.
- New pharmacy and therapeutics models that evaluate the need for new stakeholders, transitions of care, reimbursement, and maximum value for the community.
- Impact of rising drug costs and patient access, which should address the impact of drug shortages, rapid inflation, and predicted high drug costs, including the growing impact of limited drug distribution and payer-directed mandates affecting patient drug-use options.

The Council recommends this process because there are over 40 policy positions, statements, and guidelines developed by all councils.

Joint Council Task Force on ASHP Position on Assisted Suicide

The Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy met as a Joint Task Force to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following a presentation and question-and-answer session, the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors.

Value-based Drug Pricing

Council members identified the need for a definition of value-based drug pricing and suggested that more education of ASHP members and other pharmacy managers is necessary. Council members considered how value-based drug pricing is incorporated in current formulary processes. The challenges identified include the lack of integration between inpatient and outpatient formularies and the lack of information about the costs and benefits of particular medications. The Council considered how organizations will address evaluation of drugs approved by the FDA through an accelerated process that provides less data. The Council also discussed the difference between reimbursement models for inpatient and outpatient settings and how value-based drug pricing would differ between those two settings.

The Council suggested educating ASHP members through an *AJHP* editorial or primer. It was suggested that this would be a good topic for a *CPO Perspectives* column. The Council suggested that ASHP policy 1506, Premarketing Comparative Clinical Studies, and policy 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, advocate for the kinds of studies that could provide a basis for value-based drug pricing but do not address the topic of value-based drug pricing directly. The Council reviewed policy 1209, Value-Based Purchasing, and agreed the policy addresses the payer models designed for payment for patient care versus the actual pricing models for the purchase price of drugs. The Council agreed that further research could be done by reaching out to FIP members who practice in countries that have more experience with value-based drug pricing.

COUNCIL ON PHARMACY PRACTICE

POLICY RECOMMENDATIONS

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

Jennifer M. Schultz, *Board Liaison*

Council Members

Tate Trujillo, *Chair* (Indiana)
Lisa Mascardo, *Vice Chair* (Iowa)
Delaram Bahmandar, *New Practitioner* (Missouri)
Noelle Chapman (Illinois)
Mark Dunnenberger (Illinois)
Don Filibeck (Ohio)
Michael Ganio (Ohio)
Benjamin Groves, *Student* (Florida)
Jason Hutchens (Tennessee)
Joe Slechta (Kansas)
LeeAnn Miller (Connecticut)
Elizabeth Wade (New Hampshire)
Deborah Pasko, *Secretary*

1. Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use

- 1 To advocate that pharmaceutical manufacturers provide hazardous drug products
- 2 intended for home use in ready-to-administer packaging; further,

- 3 To advocate that, when hazardous drug products intended for home use are not
- 4 available from manufacturers in ready-to-administer packaging, pharmacists
- 5 repackage those drug products to minimize the risk of exposure; further,

- 6 To advocate that pharmacists provide education to patients and caregivers regarding
- 7 safe handling of hazardous drug products intended for home use.

Rationale

Home use of oral chemotherapy increases patient convenience and lowers healthcare costs, but it presents [unique safety risks](#). In a hospital or clinic setting, healthcare professionals manage the risks posed by hazardous drugs, defined as any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity ([NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings](#)). In the home environment, however, patients and caregivers must be prepared to fill that role. Ready-to-administer packaging of hazardous drugs minimizes patient, caregiver, and family exposure to hazardous drugs, promotes patient adherence, and enhances safe medication use. Ready-to-administer is defined as the product requires no manipulation before that patient

and/or caregiver can administer the medication. Versus ready-to-use packaging still may require a small amount of manipulation such as reconstitution, etc. These definitions are consistent with USP and ISMP per verbal communication. ASHP advocates that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging, and that when such packaging is not provided, pharmacists repackage those drug products to minimize exposure risk. ASHP further advocates that patients and caregivers be provided education regarding safe handling of hazardous drug products from a qualified healthcare professional, preferably a pharmacist experienced in managing the risks of hazardous drug products.

Background

The Council considered this topic in response to member suggestions and concerns expressed by the Institute for Safe Medication Practices (ISMP). The United States Pharmacopoeia (USP) has proposed a new General Chapter 800, Hazardous Drugs—Handling in Healthcare Settings, to provide standards to protect healthcare personnel who handle hazardous drugs. Chapter 800, however, does not address protection of patients, caregivers, and family members when hazardous drugs are used outside of healthcare facilities.

The Council wanted to develop policy that would encourage manufacturers to provide hazardous drugs in the most appropriate package and size conducive to patient needs to minimize exposure risk to patients, caregivers, and family members. The Council's concerns related to package type, quantities, and the safety of the container. Many chemotherapy regimens and prescriptions have predetermined quantities that are needed for the patient's protocol or regimen needs. The Council urged that packaging from manufacturers be ready to use and require as little manipulation as possible after dispensing to ensure safety and ease of use.

The Council reviewed ASHP policy position 402, Ready-To-Use Packaging for All Settings, and noted that the policy does not use the term *ready-to-administer* but rather *unit-of-use*. In the policy a "unit-of-use package" is defined as "a container--closure system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling." The Council was concerned that unit-of-use packaging may not necessarily be ready-to-administer and suggested re-titling the policy.

2. Expiration Dating of Pharmaceutical Products

- 1 To support and actively promote the maximal extension of expiration dates of
- 2 commercially available pharmaceutical products as a means of increasing access to
- 3 drugs and reducing healthcare costs; further,

- 4 To advocate that the Food and Drug Administration implement procedures to allow
- 5 pharmaceutical manufacturers to readily update expiration dates to reflect current
- 6 evidence; further,

- 7 To advocate that regulators and accreditation agencies recognize authoritative data
- 8 on extended expiration dates for commercially available pharmaceutical products.

(Note: This policy would supersede ASHP policy 9309.)

Rationale

Extending the expiration date of commercially available pharmaceutical products reduces healthcare costs and increases access. ASHP encourages pre- and post-marketing research on expiration dates and the use of the most current authoritative data on expiration dates in drug product management. The current process for updating expiration dates in drug product labeling presents barriers to timely revision, however, and should be streamlined to allow for timely updates. Until such a process is implemented, regulators and accreditation agencies should permit healthcare organizations to rely on authoritative data when determining appropriate extended expiration dates for commercially available pharmaceutical products.

Background

The Council reviewed ASHP policy 9309, Expiration Dating of Pharmaceutical Products, as part of sunset review and voted to recommend amending it as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs ~~and to recommend that pharmaceutical manufacturers review their procedures to accomplish this end;~~ further,

To advocate that the Food and Drug Administration implement procedures to allow pharmaceutical manufacturers to readily update expiration dates to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

The Council wanted to update the policy to achieve three goals: 1) clarify that the subject of the policy is commercially available pharmaceutical products; 2) address the barriers presented by the current requirements for updating drug product expiration dates in labelling; and 3) advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products, which is sometimes provided by the manufacturers themselves.

3. Primary and Preventive Care

To discontinue ASHP policy 9407, which reads:

- 1 To support primary and preventive care roles for pharmacists in the provision of
- 2 pharmaceutical care; further,
- 3 To collaborate with physician, nursing, and health-system administrator groups in
- 4 pursuit of these goals.

Background

The Council discussed ASHP policy 9407 as part of sunset review. The Council determined that the policy is redundant with the [ASHP Statement on the Pharmacist's Role in Primary Care](#) and voted to recommend discontinuation.

4. Nondiscriminatory Pharmaceutical Care

To discontinue ASHP policy 9006, which reads:

- 1 To adopt the following positions in regard to nondiscriminatory pharmaceutical care:
 - 2 • All patients have the right to privacy, respect, confidentiality, and high-
 - 3 quality pharmaceutical care.
 - 4 • No patient should be refused pharmaceutical care or denied these rights
 - 5 based solely on diagnosis.
 - 6 • Pharmacists must always act in the best interest of individual patients while
 - 7 not placing society as a whole at risk.

Background

The Council discussed ASHP policy 9006, Nondiscriminatory Pharmaceutical Care, as part of sunset review. The Council presumed that the policy was created to respond to concerns that patients with human immunodeficiency virus infection and acquired immunodeficiency syndrome would be denied privacy, respect, confidentiality, and high-quality pharmaceutical care because of their diagnoses. The Council noted that treatment of those patients has been integrated into the mainstream of pharmacy practice, concluded that the policy is redundant with the [Code of Ethics for Pharmacists](#) and other ASHP policies (e.g., ASHP policy 0101, [Pharmacy Benefits for the Uninsured](#)), and voted to recommend discontinuation.

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.)

- Elimination of Apothecary System (8613)
- Tamper-Evident Packaging on Topical Products (9211)
- Pediatric Dosing Forms (9707)
- Interventions to Reduce High-Risk Behaviors in Intravenous Drug Users (9711)
- Appropriate Dosing of Medications in Patient Populations with Unique Needs (0228)
- Pharmacist's Role in Drug Procurement, Distribution, Surveillance, and Control (0232)
- Institutional Review Boards and Investigations Use of Drugs (0711)
- Electronic Health and Business Technology and Services (0712)
- ASHP Statement on the Role of Health-System Pharmacists in Public Health (0724)
- ASHP Statement on Professionalism (0725)
- ASHP Statement on Racial and Ethnic Disparities in Health Care (0726)
- Pharmacist Prescribing in Interprofessional Patient Care (1213)
- Pharmacist's Role in Accountable Care Organizations (1214)
- Pharmacist's Role in Team-Based Care (1215)
- ASHP Statement on the Pharmacist's Role in Medication Reconciliation (1227)

Other Council Activity

Joint Council Task Force on ASHP Position on Assisted Suicide

The Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy met as a Joint Task Force to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following a presentation and question-and-answer session, the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors.

Medical Cannabis

The Council voted to recommend that the Council on Public Policy consider amendments to ASHP policy 1101, Medical Marijuana. A total of [25 states, the District of Columbia, Guam, and Puerto Rico](#) now allow for comprehensive public medical cannabis programs. Healthcare providers in those jurisdictions, including pharmacists, are grappling with the challenges presented by medical use of medical cannabis (defined for purposes of this policy as whole or parts of the natural marijuana plant and therapeutic products derived therefrom). ASHP recognizes that there is some evidence supporting the effectiveness of medical cannabis to

treat or ameliorate symptoms of disease, including nausea and vomiting associated with cancer or its treatment with chemotherapy, lack of appetite associated with human immunodeficiency virus infection or acquired immunodeficiency syndrome, chronic pain, and pediatric epilepsy.

The Council agreed that there is need for research on best practices regarding management and use of medical cannabis, and suggested that ASHP could draw on member experience to offer education and guidance on the topic. The Council specifically recognized the potential importance of the medical cannabis model adopted by [Connecticut](#), in which only pharmacists may dispense medical cannabis.

Formulary Management

Discussions have begun with ASHP that formulary management is much different now than when many policies related to this topic were developed. ASHP is currently recruiting current third-year council members to participate on a formulary advisory panel. This group will review all current ASHP policies related to formulary management and determine the future direction of this topic.

COUNCIL ON PUBLIC POLICY

POLICY RECOMMENDATIONS

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

Ranee M. Runnebaum, *Board Liaison*

Council Members

Gloria P. Sachdev, *Chair* (Indiana)
Pamela Stamm, *Vice Chair* (Georgia)
Ewa Dzwierzynski (Rhode Island)
Tara Feller, *New Practitioner* (Maryland)
Chris Fortier (Massachusetts)
Erin Fox (Utah)
Carla Frye (Nebraska)
Mark Hamm (Ohio)
Melissa A. Ortega (Massachusetts)
Michael Powell (Nebraska)
Maria Serpa (California)
Danielle Thanh, *Student* (California)
Joseph M. Hill, *Secretary*

1. Partial Filling of Schedule II Prescriptions

- 1 To advocate that state legislatures and boards of pharmacy create consistent laws
- 2 and rules that discourage overprescribing by allowing partial filling of Schedule II
- 3 drugs; further,

- 4 To advocate that public and private entities construct criteria for partial filling to
- 5 minimize the additional practice burden on pharmacists and healthcare
- 6 organizations; further,

- 7 To advocate that pharmacists educate prescribers and patients about options for
- 8 filling prescriptions for Schedule II drugs, including the risks of overprescribing, while
- 9 recognizing the patient or caregiver's rights to make their own care and management
- 10 decisions.

Rationale

The issue of opioid abuse and addiction has been at the forefront of federal and state activity. Increasing addiction rates of patients taking powerful opioids have spurred calls for action to help address this growing problem. The issue has become national in scope and has generated discussion among policymakers and healthcare practitioners alike. In mid-2016, Congress passed the [Comprehensive Addiction and Recovery Act of 2016](#), legislation aimed at curbing opioid abuse and enhancing access to addiction treatment. States have been considering their own legislative initiatives to address what is increasingly described as an epidemic.

One solution proposed by policymakers is to allow pharmacists to dispense only a portion of the quantity of a Schedule II drug prescribed (e.g., 7 days of the prescribed quantity of the drug rather than an entire 30-day supply). Such "partial filling" of Schedule II drug prescriptions

reduces the potential of opioid addiction for the patient and the risk of diversion for others. Federal law has been changed to permit partial filling of Schedule II drugs, and Massachusetts and Maine have passed laws to allow for partial filling of Schedule II drugs. ASHP advocates that other state legislatures and boards of pharmacy amend pharmacy practice acts and rules to allow for partial filling of Schedule II drugs, and that such laws and rules be made consistent across states. However, ASHP has concerns about quantity and duration limits applied across the board and not on an as-needed basis. ASHP believes that each patient must be evaluated individually and that policies that allow for partial filling are not indiscriminately applied as an across-the-board mandatory rule. ASHP encourages public and private payers to recognize the additional practice burden created by partial filling and to provide appropriate reimbursement for those activities as well as minimize the additional practice burden where possible. ASHP encourages pharmacists to serve as patient advocates by educating prescribers and patients about options for filling prescriptions for Schedule II drugs.

Background

The Council discussed this topic in response to member interest. The Council reviewed [two related ASHP policies](#) (1520, Impact of Insurance Coverage Design on Patient Care Decision, and 1504, Patient Adherence Programs as Part of Health Insurance Coverage) that mention partial filling but which focus on medication safety and medication adherence rather than partial filling's role in reducing opioid diversion and addiction. The Council identified the need for ASHP to have policy supporting shorter filling cycles for Schedule II drugs. The Council also felt that pharmacists have a role in educating prescribers and patients to establish best practices regarding opioid prescribing and partial filling. Council members pointed out the potential for an increase in diversion if partial filling is abused (e.g., when only 7 days of a 30-day prescription are filled, an opportunity for diversion of the remaining quantity is created). The Council suggested that processes for ensuring that the rest of the prescription is voided may be a way to combat diversion under this scenario.

2. Restricted Drug Distribution

- 1 To oppose restricted drug distribution systems that (1) limit patient access to
- 2 medications; (2) undermine continuity of care; (3) impede population health
- 3 management; (4) adversely impact patient outcomes; (5) erode patients'
- 4 relationships with their healthcare providers, including pharmacists; (6) are not
- 5 supported by publicly available evidence that they are the least restrictive means to
- 6 improve patient safety; (7) interfere with the professional practice of healthcare
- 7 providers; or (8) are created for any reason other than patient safety.

(Note: This policy would supersede ASHP policy 0714.)

Rationale

Restricted drug distribution systems (RDDSeS) that are not created solely for patient safety reasons significantly restrict patient access to medications. These systems were justified as a means to closely monitor patient use of medications that could potentially pose a safety risk.

They were never intended to allow drug manufacturers to reduce pharmacists' access to medications through limited distribution networks. Using restricted distribution as a tool to gain marketplace advantage rather than for patient safety undermines the justification for such limited systems. ASHP opposes the use of RDDSes for anything other than patient safety and encourages the FDA or other appropriate authorities to investigate whether RDDSes are being used in a manner inconsistent with the original intent. In addition, RDDSes may compromise continuity of care or interfere with pharmacists' accountability for care to certain patient populations, such as when an RDDS prevents a patient's pharmacist from obtaining it. Some investigational drugs approved for marketing under an RDDS are no longer available for qualifying patients on admission through the institution, despite the institution having a history of managing the drug while it was investigational. Such circumstances force the patient to seek care elsewhere or require their and their healthcare providers to unnecessarily utilize additional resources to provide care. In addition, healthcare organizations, responsible for the total care of the patient, including maintaining the patient's medical records, may lose the established patient-care relationship when a patient must go to a specialty pharmacy for a drug it cannot access. RDDSes fragment the healthcare delivery system at a time when public and private payers are increasing incentives to integrate patient care.

Background

The Council considered ASHP policy 0714, Restricted Drug Distribution, in response to a recommendation from the Council on Pharmacy Management that the Council examine whether drug manufacturers are manipulating RDDSes (e.g., risk evaluation and mitigation strategies) to gain a marketplace advantage. The Council examined the background provided by the Council on Pharmacy Management and voted to recommend policy 0714 be revised to oppose restricted drug distribution systems that have pernicious effects rather than describe a set of criteria that would make such systems acceptable. ASHP policy 0714 reads:

To affirm support for the current system of drug distribution in which prescribers and pharmacists exercise their professional responsibilities on behalf of patients; further,

To acknowledge that there may be limited circumstances in which constraints on the traditional drug distribution system may be appropriate if the following principles are met: (1) the requirements do not interfere with the continuity of care for the patient; (2) the requirements preserve the pharmacist–patient relationship; (3) the requirements are based on scientific evidence fully disclosed and evaluated by prescribers, pharmacists, and others; (4) there is scientific consensus that the requirements are necessary and represent the least restrictive means to achieve safe and effective patient care; (5) the costs of the product and any associated product or services are identified for purposes of reimbursement, mechanisms are provided to compensate providers for special services, and duplicative costs are avoided; (6) all requirements are stated in functional, objective terms so that any provider who meets the criteria may participate in the care of patients; and (7) the requirements do not interfere with the professional practice of pharmacists, prescribers, and others; further,

To advocate that the Food and Drug Administration (FDA) be granted the authority to consult with practicing pharmacists and others when the establishment of a restricted distribution system is contemplated for a drug product; further,

To advocate that FDA be granted the authority to require that manufacturers disclose all of the considerations that led to the establishment of a restricted distribution system for a specific product; further,

To advocate that FDA be granted the authority to require that manufacturers include in each restricted distribution system a mechanism that will ensure medication reconciliation and continuity of care as patients transition from one level or site of care to another; further,

To advocate that FDA be granted the authority to require manufacturers to conduct a follow-up assessment of the impact of a restricted drug distribution system.

3. Collaborative Drug Therapy Management

- 1 To pursue the development of federal and state laws and regulations that authorize
- 2 collaborative drug therapy management by pharmacists; further,

- 3 To advocate expansion of federal and state laws and regulations that optimize
- 4 pharmacists' ability to provide the full range of professional services within their scope
- 5 of expertise; further,

- 6 To advocate for state laws and regulations that would allow pharmacists to transmit
- 7 prescriptions electronically under collaborative drug therapy management protocols;
- 8 further,

- 9 To acknowledge that as part of these advanced collaborative practices, pharmacists, as
- 10 active members in team-based care, must be responsible and accountable for
- 11 medication-related outcomes; further,

- 12 To support affiliated state societies in the pursuit of state-level collaborative drug
- 13 therapy management authority for pharmacists.

(Note: This policy would supersede ASHP policy 1217.)

Rationale

Although more than 43 states permit collaborative drug therapy management (CDTM), there is great variability in the authority granted to pharmacists engaged in CDTM. ASHP supports CDTM and advocates its expansion to all states, in a variety of diverse practice settings, and at the highest level of pharmacy practice. As new pharmacy practice models emerge, CDTM should be a part of those innovations. One of the common barriers to the highest level of CDTM is the prohibition of pharmacists transmitting prescriptions electronically under CDTM

protocols. The expansion of CDTM, including electronic transmission of prescriptions, will aid in moving the profession forward to the highest level of interprofessional, team-based practice and will enable pharmacists to practice at the top of their licenses, accountable to the patient and the team for medication-related outcomes.

Background

The Council reviewed ASHP policy 1217, Collaborative Drug Therapy Management, in response to a recommendation from the House of Delegates and voted to recommend amending it as follows (underline indicates new text; ~~striketrough~~ indicates deletions):

To pursue the development of federal and state ~~legislative and regulatory provisions~~ laws and regulations that authorize collaborative drug therapy management by pharmacists; further,

To advocate expansion of federal and state ~~legislative and regulatory provisions~~ laws and regulations that optimize pharmacists' ability to provide the full range of professional services within their scope of expertise; further,

To advocate for state laws and regulations that would allow pharmacists to transmit prescriptions electronically under collaborative drug therapy management protocols; further,

To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication-related outcomes; further,

To support affiliated state societies in the pursuit of state-level collaborative drug therapy management authority for pharmacists.

While CDTM laws recognize the ability of pharmacists to prescribe in accordance with a CDTM agreement, e-prescribing systems consistently do not recognize pharmacists as prescribers, which is a barrier to pharmacist patient care. The delegates who proposed this topic felt that ASHP should advocate for state CDTM laws that include pharmacists as providers in e-prescribing systems to reflect pharmacists' patient-care roles under CDTM. As states update their CDTM laws and regulations to reflect modern care delivery, they must also account for the use of e-prescribing systems used by pharmacists as part of the CDTM agreement.

While the Council on Public Policy is responsible for developing policy related to state, federal, and local laws and regulations, this policy has implications beyond the scope of the Council. For example, although the policy calls for ASHP to advocate for state CDTM laws to account for pharmacists prescribing using the e-prescribing systems, it does not include any advocacy that software developers account for collaborative practice agreements where pharmacists are prescribing pursuant to protocol. Therefore, the Council felt that some additional action items by ASHP are warranted. The Council made the following recommendations:

- The Section on Pharmacy Informatics and Technology should work with electronic medical record providers to allow for pharmacists to use the e-prescribing systems in states where collaborative practice allows prescribing pursuant to protocol.
- ASHP should publish the National Provider Identifier (NPI) taxonomy sheet as a resource, making it available to members. The background documents the Council reviewed included a document that described a workaround with respect to e-prescribing systems. Council members felt that this workaround document could be a key element of a resource page created to educate pharmacists on e-prescribing systems and collaborative practice.
- ASHP should provide education to its members on obtaining NPI numbers and, in particular, educate state affiliates to encourage their members to obtain NPI numbers.

4. Greater Competition Among Generic and Biosimilar Manufacturers

- 1 To support legislation and regulations that promote robust competition among
- 2 authorized generic and biosimilar pharmaceutical manufacturers.

(Note: This policy would supersede ASHP policy 0222.)

Rationale

A healthy market for generic drug products and biosimilars increases patient access to drugs and lowers drug costs. ASHP recognizes several threats to the health of that market and advocates legislative and regulatory solutions: speeding FDA approval of generic drug applications, especially for lifesaving drugs; reducing drug monopolies by incentivizing competition for additional market entrants; targeting exclusivity protections to truly innovative products; and curbing abuse of risk evaluation and mitigation strategies (REMS). In 2015, the FDA faced a backlog of nearly 4,000 generic drug applications, with the approval process taking three years or more. ASHP advocates that the FDA be provided the resources needed to evaluate and approve generic drug applications in a safe and timely manner. ASHP also advocates government and market incentives to increase competition for expensive drugs where no competitors exist and encourage additional market entrants. ASHP has long recognized that agreements between generic and brand-name manufacturers when a product's market exclusivity is about to expire have the effect of delaying the marketing of competitor products and limiting patient access to affordable generic drugs. ASHP advocates for legislative and regulatory solutions to limit such agreements, as well as solutions to prevent brand-name manufacturers from extending market exclusivity and preventing market entry by generics by slightly altering the formulation of a product. ASHP further advocates legislation that would prevent frivolous patent infringement litigation by brand-name manufacturers, which is reported to have been initiated with the sole intent to extend market exclusivity. Another solution advocated by ASHP is curbing misuse of REMS, which are reported to have been used to prevent generic manufacturers from accessing drug products. In addition, ASHP advocates

for more consumer-accessible information on drug prices, including an annual report on increases in drug prices, which would provide patients and their healthcare providers with the information they need to make drug purchasing choices. Finally, ASHP encourages [appropriate federal review of anticompetitive practices](#) by pharmaceutical manufacturers.

Background

The Council reviewed ASHP policy 0222, Greater Access to Less Expensive Generic Medications, and voted to recommend amending it as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To support legislation and regulations that promote ~~greater patient access to less expensive generic drug products~~ robust competition among authorized generic and biosimilar pharmaceutical manufacturers.

The Council discussed this topic at length and considered changes to it given recent changes in the marketplace and the impact that skyrocketing drug prices have had on hospital pharmacy budgets and patient access to care. The Council felt that the pharmaceutical industry has been thwarting competition that would help drive down prices. The Council cited practices such as pay for delay, where a brand name company pays a fee to a potential generic competitor to stay out of the market for a certain period of time. In its discussion, the Council noted the need for transparency, patient choice in therapeutic alternatives, and patient knowledge of drug costs. Transparency was discussed within the context of research and development costs and the source of funding for research and development, such as the National Institute of Health. Further, the Council discussed transparency in how prices are developed and how manufacturers justify the value of their products. Ultimately, the Council kept the policy language broad, with a focus on competition and value. Both competition and value are contained in the policy platform of [the Campaign for Sustainable Rx Pricing \(CSRxP\)](#), a broad coalition of stakeholders including payers, clinicians, hospitals, retailers, and seniors. The CSRxP was formed to help address the growing problem of skyrocketing drug prices. The Council voted to include these two broad policy objectives in the new policy language. The third policy platform item developed by CSRxP, transparency, was left out of the policy over concern that transparency could extend to contract pricing and negotiated transactions that are considered proprietary in nature.

The Council also discussed steps that pharmacists can take to help alleviate the problem. Therapeutic substitution has long been used by pharmacists to give patients access to less expensive generic medications. The Council reaffirmed its support of therapeutic substitution. Additionally, the Council recommended that the rationale for this policy refer to existing ASHP policy 0814, [Federal Review of Anticompetitive Practices by Drug Product Manufacturers](#). This policy opposes anticompetitive practices by manufacturers that adversely affect drug product availability and price.

5. Drug Testing

- 1 To recognize the use of pre-employment and random or for-cause drug testing during
- 2 employment based on defined criteria and with appropriate testing validation
- 3 procedures; further,

- 4 To support employer-sponsored drug programs that include a policy and process that
- 5 promote the recovery of impaired individuals; further,

- 6 To advocate that employers use validated testing panels that have demonstrated
- 7 effectiveness detecting commonly abused or illegally used substances.

(Note: This policy would supersede ASHP policy 9103.)

Rationale

Controlled substance diversion and abuse has reached the attention at the highest levels in the U.S., with even the White House weighing in on the crisis. In the past 4-5 years, the Drug Enforcement Administration has levied large fines on chain drugstores, drug wholesalers, and even major hospitals. Pharmacy managers and pharmacists-in-charge have increasing responsibility of ensuring controlled substance management and storage across large healthcare organizations. There is an increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and many challenges exist for healthcare institutions in managing controlled substances.

ASHP recognizes that drug testing job applicants and employees whose responsibilities may bring them into contact with controlled substances is an essential element of diversion prevention programs. Pre-employment and random or for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances. In addition, drug testing should be supported by an employee addiction recovery program, as outlined in the [ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance](#).

Background

The Council reviewed ASHP policy 9103, Drug Testing, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text):

To recognize the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

The Council found the policy to still be relevant but voted to amend the policy to support healthcare organizations who wish to conduct random drug screening as part of a diversion control program.

The Council on Pharmacy Management recommended adding two additional items to the policy. The first was language to specify the use of validated testing panels that have demonstrated effectiveness in identifying the presence of substances commonly abused. The Council voted to accept that addition. The second was a suggestion that a positive employee drug test should trigger a follow-up test for infectious disease. The reasoning was based on an event in which a healthcare practitioner who was abusing controlled drugs placed used needles into inventory. The employee had hepatitis C, and the re-used needles eventually infected patients who used the same needles. The Council considered this addition but decided against including it in this amended policy. The Council agreed on the need for additional infectious disease screening but concluded that such testing was something that should be addressed in the healthcare organization's drug diversion policies and procedures rather than its drug testing policy. This decision was communicated to the Chair of the Council on Pharmacy Management, who agreed that this provision was more appropriate in a drug diversion policy.

6. Codes on Solid Dosage Forms of Prescription Drug Products

To discontinue ASHP policy 8709, which reads:

- 1 To support efforts requiring manufacturers of solid dosage form prescription drug
- 2 products to imprint a readily identifiable code indicating the manufacturer of the drug
- 3 product and the product's ingredients; further,
- 4 To make information on translation of the codes readily available.

Background

The Council reviewed ASHP policy 8709 as part of sunset review and concluded that it is no longer needed as federal law ([21 C.F.R. § 206.10](#)) reflects this policy. The Council noted the pharmacist or pharmacy may be required to print on the label a description of the imprint code and suggested that the appropriate ASHP council investigate whether ASHP policy regarding the requirement needs to be developed.

7. Intermediate Category of Drugs

To discontinue ASHP policy 0220, which reads:

- 1 To support, with appropriate changes in federal statutes and regulations, the
- 2 establishment of an intermediate category of drug products that do not require a
- 3 prescription but are available only from pharmacists and licensed healthcare
- 4 professionals who are authorized to prescribe medications; further,

5 To base such support on the following facts:

6 1. Some drug products that are potential candidates for switching from prescription-
7 only to nonprescription status raise concerns about patient safety as nonprescription
8 products; these products could be better controlled, monitored, and evaluated by
9 making them available only from pharmacists and licensed healthcare professionals
10 who are authorized to prescribe medications; and

11 2. Pharmacists have the education, training, and expertise to help patients make
12 appropriate therapeutic decisions associated with the use of such drug products.

13 Further,

14 To support that the regulatory system for this intermediate category of drug products
15 contain the following features:

16 Drug products appropriate for this intermediate category would be identified through
17 the advice of pharmacists, physicians, and other licensed health professionals who
18 are authorized to prescribe medications, on the basis of the medical conditions to be
19 treated and potential adverse effects (as indicated in FDA-approved labeling);

20 Pharmacists would be able to provide drugs in this intermediate category directly to
21 patients without a prescription, on the basis of appropriate assessment and
22 professional consultation;

23 Licensed health professionals who currently have prescribing authority would
24 continue to have the ability to prescribe medications in this intermediate category;
25 and

26 Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-
27 reaction reporting would be collected to help determine a drug product's eventual
28 movement to nonprescription status, return to prescription-only status, or
29 continuation in the intermediate category.

Background

The Council reviewed ASHP policy 0220 as part of sunset review and concluded that it is no longer needed because it is redundant with the [ASHP Statement on Criteria for an Intermediate Category of Drugs](#).

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.)

- Employee Testing (9108)
- Drug Samples (9702)
- Pharmacist Recruitment and Retention (0218)
- FDA Authority to Prohibit Reuse of Brand Names (0719)
- Standardizing Prefixes and Suffixes in Drug Product Names (0720)
- Pharmacy Technicians (1216)
- Stable Funding for HRSA Office of Pharmacy Affairs (1219)

Other Council Activity

Joint Council Task Force on ASHP Position on Assisted Suicide

The Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy met as a Joint Task Force to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following a presentation and question-and-answer session conducted by [Dr. Mark Hughes](#), the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors.

Medical Marijuana

The Council recommended that ASHP develop materials intended to help hospitals who come into contact with patients using medical marijuana. There are currently no guidelines on how hospitals handle patients who are using cannabis for medical purposes. The Council noted that there may not be a need for new policy but urged ASHP to explore options such as networking sessions or blinded surveys to gain an understanding of what, if anything, hospitals and health systems currently do. A recommendation made by the 2015 ASHP House of Delegates asked ASHP to examine ASHP policy on the regulation of dietary supplements. Relevant ASHP policies include 0801, 1305, 0920, 0811, and 0415.

The Council concluded that existing ASHP policy on the regulation of dietary supplements is adequate. One area of potential concern is the growing use of homeopathic medicines. After discussion, the Council decided that homeopathic medications are not entirely within the Council's purview and that the Council on Therapeutics may want to investigate this issue further.

Exploring Drug Pricing Transparency

The Council discussed this along with the issues raised above with respect to a marketplace that has robust competition. In lieu of the revised policy 0222, the Council felt that new policy that captures competition, transparency, and value should be explored. Additionally, the Council Chair urged this policy to be developed during this policy year.

Pharmacists in State Medicaid Programs

The Council reviewed several ASHP policies and identified two volunteers to further explore ASHP policy and draft potential policy language for consideration at a future meeting. Specifically, the area of interest is sustainability and reimbursement within Medicaid. The National Governors Association report from 2015 includes a table that outlines services and reimbursement provided by pharmacists in state Medicaid programs. The Council will explore policy that attempts to standardize services and reimbursement rather than create a patchwork of state rules in this area.

Medicaid Program and the Affordable Care Act (ACA)

The Council was informed that Congress is considering block granting Medicaid funding to states. One member suggested that ASHP explore a policy position that would describe the basic elements that Medicaid programs should provide. The Council discussed several options for sharing information with members about provider status recognition, state Medicaid programs, and ACA repeal and replacement. The Council concluded that a white paper would be the best option and should be discussed at the next internal ASHP policy meeting.

21st Century Cures Act

The Council requested that the Council on Therapeutics review the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control in light of the Act.

COUNCIL ON THERAPEUTICS

POLICY RECOMMENDATIONS

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

Donald E. Letendre, *Board Liaison*

Council Members

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Amy S. Sipe, *Vice Chair* (Missouri)
Karen Berger (New York)
Snehal Bhatt (Massachusetts)
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Kurt Mahan (New Mexico)
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Katie Morneau (Texas)
Nathan Pinner (Alabama)
Jodi L. Taylor (Tennessee)
Mary Vincent, *New Practitioner* (Ohio)
Vicki Basalyga, *Secretary* (Maryland)

1. Therapeutic and Psychosocial Considerations of Transgender Patients

- 1 To support medication and disease management of transgender patients as a part of
- 2 care unique to this population; further,

- 3 To advocate that transgender patients have access to pharmacist care to ensure safe
- 4 and effective medication use; further,

- 5 To promote research on, education about, and development and implementation of
- 6 therapeutic and biopsychosocial best practices in the care of transgender patients;
- 7 further,

- 8 To encourage documentation of a patient's birth sex and identified gender in the
- 9 patient medical record.

Rationale

The transgender population is a small population that has unique healthcare and biopsychosocial needs. There are [guidelines](#) to help practitioners caring for the patients identify these needs and recommendations for practitioners to consider.

Patients electing to transition from their birth sex to their identified gender may have surgeries and take higher doses of hormones to change their physical appearance to reflect their identified sex. These patients have significant requirements for therapeutic drug monitoring, as certain lab values may appear out of normal limits but are clinically appropriate for the transgender patient and risk of drug-drug interactions may be higher because medications may be taken at a higher than normal doses. These patients may be more at risk for adverse effects,

including thyroid disorders, and may more frequently require anticoagulation and management of diabetes as a result of medication therapy. Other unique needs of these patients include cardiovascular and thrombotic risk assessment, screening for certain types of cancers should they elect to keep their gonadal organs, and other associated primary care screenings associated with their birth sex. Considerations for transgender patients who wish to have children will add the complexity of fertility as well as attention to use of teratogenic medications to their needs. Because of the unique and complex healthcare needs of transgender patients, it is essential that they have adequate access to appropriate care, including pharmacist care. To help ensure appropriate assessment and treatment, a patient's birth sex and identified gender should be documented in the patient medical record. This documentation also helps healthcare providers address another of the unique biopsychosocial needs of transgender patients; like other healthcare providers, pharmacists should address transgender patients by their identified gender.

Background

The Council discussed the definitions used in providing care to meet the unique clinical and social needs of transgender patients. A review of available research and guidelines revealed that there are no clinically significant changes in a person's pharmacodynamic or pharmacokinetic parameters when transitioning from birth sex to identified gender. In addition, the Council discussed the biopsychosocial aspects of caring for transgender patients. The Council reviewed recent cases in which addressing patients by the name associated with their birth sex during, despite requests to be called by the name associated with their identified gender, resulted in self harm and death. Finally, the Council discussed the discrimination transgender patients may face and the importance of access to care and of ensuring equitable care.

2. Pharmacist's Leadership Role in Glycemic Control

- 1 To advocate that pharmacists provide leadership in caring for patients receiving
- 2 medications for management of blood glucose; further,

- 3 To advocate that pharmacists be a member of the interprofessional healthcare team
- 4 that coordinates glycemic management programs; further,

- 5 To encourage pharmacists who participate in glycemic management to educate
- 6 patients, caregivers, prescribers, and other members of the healthcare team about
- 7 glycemic control medication uses, metrics, drug interactions, adverse effects, the
- 8 importance of adhering to therapy, access to care, and recommended laboratory
- 9 testing and other monitoring.

Rationale

As medication experts, pharmacists play a key role in implementation, maintenance, monitoring, management of complications, risk assessment, and assurance of continuity of care for patients receiving medications for management of blood glucose. Inappropriate medication-related management of diabetes creates unnecessary, preventable harm. There is a direct relationship between medication administration and harm from inappropriately managed glycemic agents. In 2014, the [Accountability Measures Work Group](#) identified the incidence of hypoglycemic and hyperglycemic events and evidence of poorly controlled diabetes (hemoglobin A1C value exceeding 9%) as clinical measures for pharmacist accountability. Given this responsibility, pharmacists need to provide leadership in caring for patients receiving medications for management of blood glucose, including education of patients and members of the interprofessional healthcare team. To enhance their ability to participate in the care of these patients, many pharmacists have elected to become certified diabetes educators. This training strengthens the value of pharmacists and permits them to be more aligned with the benchmarking tools linked with reimbursement models. The unknown adverse effects of sustained hyperglycemia in the inpatient and outpatient settings, as well as during transitions of care, demonstrate a continued need for pharmacist-led research in both all settings.

Background

The Council created this policy after discussion of the 2014 [Pharmacy Accountability Measures Work Group](#) recommended clinical measures for pharmacy accountability. The Council reviewed all ASHP policies, statements, and guidelines and found there are no policies on glycemic control despite its identification by the Accountability Measures Work Group as one of four clinical measures for pharmacist accountability. The Council supported education and collaborative development of practice recommendations. The Council also recommended education through webinars or educational sessions, developing resources that address transition of care, encouraging research opportunities for ambulatory care pharmacists, and potential development of a best practices document or minimum standard regarding glycemic management.

3. Drug Dosing in Diseases That Modify Pharmacokinetics or Pharmacodynamics

- 1 To encourage research on the pharmacokinetics and pharmacodynamics of drugs in
- 2 acute and chronic disease states; further,

- 3 To support development and use of standardized models, laboratory assessment,
- 4 genomic testing, utilization biomarkers, and systemwide documentation of
- 5 pharmacokinetic and pharmacodynamic changes in acute and chronic disease states;
- 6 further,

- 7 To collaborate with stakeholders in enhancing aggregation and publication of and access
- 8 to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug
- 9 dosing within these patient populations.

Rationale

The pharmacokinetic and pharmacodynamic properties of drugs found in drug information monographs are based on the drug's absorption, distribution, metabolism, and excretion in healthy, adult patients during Phase I of a drug's clinical trials. Many patients receiving medication therapy do not fit this profile, and many have compromised organ function. The medical community has long recognized the need for a standardized approach to evaluating organ system dysfunction. Although there are methods to determine organ function (e.g., the Cockcroft-Gault equation for renal function or the Child-Turcotte-Pugh Classification for Severity of Cirrhosis), there is debate as to whether these methods are true indicators of organ function, as the components that comprise these equations may fluctuate based on severity and disease status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

In addition, with the exception of adjustments for renal dysfunction, there is not much information regarding dosage adjustment for specific medications. Many organ systems are involved in a drug's absorption, distribution, metabolism, and excretion. Hepatic effects, for example, are a risk area, as those effects are slower to be seen and have not been the subject of as much research, and the number of drugs affected are smaller in number than renally excreted drugs. Both acute and chronic aspects of disease may require monitoring and adjustment, including sepsis, encephalopathies, pregnancy, heart failure exacerbations, and cystic fibrosis, and certain protocols such as therapeutic hypothermia can also have clinically significant impact on a drug's pharmacokinetic and pharmacodynamic behavior. There is also need to promote research and utilization of biomarkers into practice, as these may reflect organ function and may provide pharmacists with a more complete clinical picture.

Background

The Council identified the need for a standardized approach for evaluating organ system dysfunction as well as the evolution of pharmacists' understanding of pharmacokinetics and pharmacodynamics, particularly the work of [Meindert Danhof](#), whose emerging pharmacokinetic and pharmacodynamic theoretical concepts include physiology-based models in which disease states play an important role.

4. Clinical Significance of Extremes of Weight and Weight Changes

- 1 To encourage pharmacists to participate in interprofessional efforts to ensure
- 2 appropriate patient height and weight are recorded in the patient medical record to
- 3 provide safe and effective drug therapy to patients who may fall outside normal
- 4 weight parameters or experience clinically significant changes in weight in a short
- 5 period of time; further,

- 6 To encourage drug product manufacturers to conduct pharmacokinetic and
- 7 pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes
- 8 of weight and weight changes to facilitate safe and effective dosing of drugs in these
- 9 patient populations, especially for drugs most likely to be affected by weight; further,

- 10 To encourage independent research on the clinical significance of extremes of weight
- 11 and weight changes on drug use, as well as the reporting and dissemination of this
- 12 information via published literature, patient registries, and other mechanisms;
- 13 further,

- 14 To advocate that clinical decision support systems and other information
- 15 technologies be structured to facilitate prescribing and dispensing of drugs most
- 16 likely to be affected by extremes of weight and weight changes.

Rationale

Patients who have clinically significant changes in weight during an admission or between physician visits, or who are at an extreme high or low weight, have a higher risk of medication dosing errors that depend on weight body surface area. Accurate heights and weights in SI units (i.e., kilograms, grams, meters, and centimeters) are an integral part of a physical examination for pharmacists to ensure proper dosing of medications. Certain medications require dosing based on body surface area, and there is a need for healthcare organizations to consistently record patients' height, as estimation of height or weight can contribute to potential over- or underdosing.

Factors such as clinically significant changes in weight due to fluid overload and subsequent diuresis, patient growth, and weight changes due to changes in caloric consumption complicate the picture of an appropriate weight to record for dosing certain medications. Some healthcare organizations default to a dosing weight that is used for dosing medications alone, while other weight fluctuations recorded on a daily basis are not used to dose medications, whereas other organizations alert pharmacists to a clinically significant change in weight. Leveraging technology to ensure such safeguards are in place is essential, and providing interoperability between the patient's recorded dosing weight and smart pumps is ideal.

Pharmacists are also seeing an increase in the number of patients at both extremes of weight, and there is a lack of information regarding dosing medications for these populations. ASHP advocates that the Food and Drug Administration (FDA) develop guidance for voluntary drug dosing studies in these populations, as the need for this guidance is supported by the complexity of drug dosing that can vary based on drug and patient characteristics. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies, especially for drugs for which significant weight extremes may have clinical impact.

Background

The Council discussed the challenges of determining an appropriate dosing weight for patients and the inherent safety risk in changing a patient's weight too frequently, which can lead to dosing errors, especially when smart pumps are used to titrate vasoactive, pain, or antithrombotic medications. The Council also recognized that there are medications that do not

require dose changes even when there is a dramatic change in a patient's weight. The Council also encouraged ASHP advocate for independent clinical and practice-based research to further define clinical use of drugs in the treatment of these populations, as well as clinician reporting of patient experience in articles and clinical registries.

5. Pain Management

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

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

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

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

- 12 To foster the development of educational resources on multimodal pain therapy,
- 13 substance abuse and prevention of adverse effects, further

- 14 To encourage the education of pharmacists, pharmacy students, and other
- 15 healthcare providers regarding the principles of pain management.

(Note: This policy would supersede ASHP policy 1106).

Rationale

Currently there are over 100 million adults in the United States affected by acute and chronic pain. Pain management requires ongoing assessment and reassessment of analgesia, activities of daily living and adverse effects. Pharmacists are well poised to a key role in appropriate treatment and optimization of severe pain and chronic pain with multimodal treatment strategies. Pain therapies, in particular, have the potential for abuse if not used appropriately. ASHP is cognizant of the delicate balance between undertreatment of pain and barriers to patient access that can occur with the implementation of abuse-prevention strategies. ASHP advocates increased awareness of the abuse and misuse of some pain therapies and encourages pharmacists to take a lead role in identifying and preventing inappropriate use through individual clinician efforts (e.g., prescriber and patient education on the potential for

abuse) and system-based approaches (e.g., use of information technology systems to monitor for trends that suggest inappropriate prescribing or patient use).

Background

The Council reviewed ASHP policy 1106 as a part of the discussion of the clinical measures for pharmacy accountability recommended by the 2014 [Pharmacy Accountability Measures Work Group](#) and recommended amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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 foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects; further,

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

The Council reviewed all policies, statements and guidelines by ASHP and recommending adding to policy 1106, language that addressed the role of multimodal pain therapy, substance abuse and prevention of adverse effects as these aforementioned areas are becoming increasingly present in management of pain. Furthermore, the Council also recommended removing mention of methods to minimize drug diversion, as this is addressed in ASHP policy 1614, [Controlled Substance Diversion and Patient Access](#).

6. Clinical Investigations of Drugs Used in Elderly and Pediatric Patients

- 1 To advocate for increased enrollment and outcomes reporting of pediatric and
- 2 geriatric patients in clinical trials of medications; further,

- 3 To encourage drug product manufacturers to conduct pharmacokinetic and
- 4 pharmacodynamic research in pediatric and geriatric patients to facilitate safe and
- 5 effective dosing of medications in these patient populations.

(Note: This policy would supersede ASHP policy 0229.)

Rationale

Pediatric and geriatric patients are populations in which the pharmacokinetic and pharmacodynamic properties of medications may differ from those typically seen in an adult patient. These differences can dramatically alter the behavior of drugs, producing supra- or subtherapeutic levels, which may result in adverse effects. While there has been legislation that provides incentive for drug manufacturers to study these effects, many drugs already approved by the FDA do not have such information or robust outcomes reporting for these at-risk populations. The need for this guidance is supported by the complexity of drug dosing for these patients, which varies based on drug and patient characteristics. A paucity of research in these patient populations is noted, which is similar to the lack of preapproval studies in obese patients. ASHP also encourages independent clinical and practice-based research to further define clinical use of drugs in the treatment of these patients, as well as clinician reporting of patient experience via published articles and clinical registries.

Background

The Council reviewed ASHP policy 0229 as part of sunset review and recommended amending it as follows (underline indicates new text; ~~strike through~~ indicates deletions):

To advocate for increased enrollment and outcomes reporting of pediatric and geriatric patients in clinical trials of ~~new~~ medications; further,

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric and geriatric patients to facilitate safe and effective use of medications in these patient populations.

The Council found the policy relevant but concluded it needed to be updated and broadened to include outcomes reporting and to include trials of all medications rather than just new medications. The language used in ASHP policy 1515, [Research on Drug Use in Obese Patients](#), was adopted, as the Council concluded that this language captured the essence of the needed policy.

7. Safe and Effective Therapeutic Use of Invertebrates

- 1 To recognize use of medical invertebrates as an alternative treatment in limited
- 2 clinical circumstances; further,

- 3 To educate pharmacists, patients, and the public about the risks and benefits of
- 4 medical invertebrates use and about best practices for use; further,

- 5 To advocate that pharmacy departments, in cooperation with other departments,
- 6 provide oversight of medical invertebrates to assure appropriate formulary
- 7 consideration and safe procurement, storage, control, prescribing, preparation,
- 8 dispensing, administration, documentation, clinical and regulatory monitoring, and
- 9 disposal; further,

- 10 To encourage independent research and reporting on the therapeutic use of medical
- 11 invertebrates.

Rationale

Medical invertebrates, including leeches and maggots, are increasingly used in practice, including in treatment of extravasation injury, post-plastic-surgery salvage, relief of vascular congestion, macroglossia, compartment syndrome, pain management, and debridement therapy. The use of medical invertebrates is not without risk. There have been reports of local and systemic infections with use of leeches and transmission of communicable disease if not handled properly, and use may mask coagulopathies. Antimicrobial prophylaxis may be required, and there are also drug-invertebrate interactions that may impact the effectiveness of invertebrate therapy, and. There is also limited research on the efficacy of these therapies that lead to varied practice and unsubstantiated claims.

Background

There is a lack of evidence regarding many facets of leech and maggot therapy and lack of guidance regarding documentation in the electronic health record. There is also an absence of best practices regarding procurement, storage, use, and disposal of leeches and maggots. Many healthcare organizations that use medical invertebrates are storing, ordering, and utilizing leeches based on recommendations of the single source. These recommendations do not adequately cover appropriate indications for use, the ordering of leeches through an electronic medical record (EMR), or antimicrobial prophylaxis for medical leeches. Use of maggot therapy for debridement presents similar policy challenges. The Council identified the need for more education regarding appropriate patient selection (e.g., use for vascular congestion, not for ischemia or compartment syndrome) and management or avoidance of concomitant therapy (e.g., caffeine, vasoconstrictors). More research is also needed regarding the appropriate selection and duration of antimicrobial prophylaxis for medicinal leech therapy as well as the need for promotion of ordering medical leech therapy through EMR, which is needed for appropriate screening, documentation, and facilitation of adjunctive therapies. The Council also recognized the need for aid in developing policies for handling, sacrifice, and disposal. As with many nontraditional therapies, there are unsubstantiated healing claims of alternative medicine clinics and therefore, more research is needed on appropriate indications for use as well.

8. Drug Dosing in Extracorporeal Therapies

- 1 To encourage research on the pharmacokinetics and pharmacodynamics of drug
- 2 dosing in extracorporeal therapies; further,

- 3 To support development and use of standardized models of assessment of the
- 4 pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies;
- 5 further,

- 6 To collaborate with stakeholders in enhancing aggregation of data on the
- 7 pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies.

(Note: This policy would supersede ASHP policy 1606.)

Rationale

There are few resources and recommendations for drug dosing in patients receiving the varied forms of extracorporeal therapies, including renal replacement therapy, extracorporeal membrane oxygenation (ECMO) support, apheresis, plasmapheresis, molecular adsorbent recirculating system (MARS) support, single pass albumin dialysis (SPAD), fractionated plasma separation and adsorption (PROMETHEUS), therapeutic plasma exchange (TPE), extracorporeal liver assist device (ELAD) support, modular extracorporeal liver (MELS) support, peritoneal dialysis, and use of ventricular assist devices.

Appropriate dosing is a very important in optimizing patient outcomes and achieving goals of therapy. Often, drug properties are used to make educated guesses on appropriate dosing and are based on estimations of clearance. In the critically ill population, serious infections and renal issues often occur simultaneously. Solute removal has a significant impact on dosing and appropriate dosing. Many patient characteristics and device variables need to be considered when dosing patients receiving these therapies. These factors include flow rate, membrane pore size, volume of distribution, and patient status. Protein binding helps sustain the drug in tissue, and drugs with a large molecular weight may clog the porous membranes. There is a scarcity of research on drug removal by these extracorporeal means, and ASHP encourages independent clinical and practice-based research to further define clinical use of drugs for patients receiving these modes of treatment as well as clinician reporting of patient experience via published articles and clinical registries.

Background

A 2016 House of Delegates recommendation urged the Council to consider a policy to encourage research on drug removal by extracorporeal means to facilitate drug dosing support. The Council recognized that there are multiple modalities of extracorporeal support and treatment and concluded that ASHP policy 1606, Drug Dosing in Renal Replacement Therapy,

should be amended to include all extracorporeal modalities, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies ~~renal replacement therapy~~; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies ~~renal replacement therapy~~; further,

To collaborate with stakeholders in enhancing aggregation of data on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies ~~renal replacement therapy~~.

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.)

- Criteria for Medication Use in Geriatric Patients (1221)
- Medication Adherence (1222)
- Globalization of Clinical Trials (1223)

Other Council Activity

CPIC Guidelines

The Council voted to endorse the CPIC Guidelines on HLA-B Genotypes and Dosing of Allopurinol and the CPIC Guidelines on CYP3A5 Genotypes and Dosing of Tacrolimus.

The Council reviewed two [Clinical Pharmacogenomics Implementation Consortium](#) guidelines. The Council acknowledged that the development of these recommendations closely adheres to Institute of Medicine recommendations on developing rigorous and trusted clinical practice guidelines. The Council appreciated the focus on interpretation of genetic tests rather than appropriateness of testing. Previous councils have found value in this type of guidance to aid in practice.

Antibiotic-Impregnated Delivery Systems

The Council reviewed current ASHP policy to determine where it addressed practice issues related to antibiotic-impregnated delivery systems and concluded that the [ASHP Statement on the Pharmacist's Role With Respect to Drug Delivery Systems and Administration Devices](#), ASHP policy 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, and ASHP policy 1313, Drug-Containing Devices, address the topic to the Council's satisfaction but since much of this practice occurs behind closed doors, thought that high visibility is needed on the subject. The Council made the following recommendations.

- Stewardship Component: ASHP should advocate that antimicrobial stewardship programs ensure that antibiotics used in antibiotic bone cement or beads is documented in the medical record, including type and amount used, and monitored for resistance trends, management of shortages, and use.
- FDA and Manufacturers: ASHP should encourage manufacturers to make, and the FDA to approve, more commercially available products in concentrations commonly used in practice.
- Education, Tools, and Research: ASHP should promote awareness of the use of antibiotic-impregnated delivery systems through multiple channels, including webinars,

presentations at ASHP meetings, networking sessions, ASHP Connect, and the ASHP website. ASHP should also advocate for research on the non-FDA-approved drug/cement mixtures for stability and elution properties, evaluation of resistance trends, prolonged exposure, management of allergic reactions and/or adverse effects, and the use of impregnated cement for treatment versus prophylaxis.

- **Guidelines and Best Practices:** ASHP should reach out to a medical organization (e.g., American Academy of Orthopaedic Surgeons or Infectious Diseases Society of America) to develop best practices regarding use of antibiotic-impregnated delivery systems, including compounding, adverse drug events, and therapeutic monitoring and research. The Council further recommended reviewing the [ASHP Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery](#) to address and expand on the issues identified by the Council.

Pharmacist Accountability Measures: Antimicrobial Stewardship

The Council reviewed current ASHP resources and activities supporting the ASHP [Accountability Measures](#) for Antimicrobial Stewardship. After review, the Council made the following recommendations.

- **Recommendation to Council to Practice Management:** To consider developing policy to advocate for workforce changes to meet the anticipated need regarding adequate support of pharmacist time, resources, and staff to fulfill antimicrobial stewardship program activities. There is a concern that these requirements will overcommit pharmacists who already have a large workload and that there should be dedicated pharmacist resources for this role.
- **Recommendation to Council on Education and Workforce Development:** To consider developing policy to advocate that pharmacy schools consider antimicrobial stewardship as part of the educational curriculum.
- **General Recommendations:** ASHP should explore development of minimum competencies for pharmacist leaders and pharmacist participants, including development of a traineeship for pharmacist leaders with a mentorship component. ASHP should also explore resources to address the needs of institutions implementing an antimicrobial stewardship program.

Clinical Alternatives for High-Cost Drugs

The Council acknowledged that high drug costs are a multifaceted problem stemming from multiple causes, including single suppliers of both new and generic drugs. The Council noted the parallel discussion by the Council on Practice Management regarding this timely and important topic and agreed that the topic would best be addressed through a larger discussion among ASHP councils. The Council recognized that many of the aspects of the topic discussed were outside of the purview of the Council but suggested that they would be willing to serve as a resource to other councils on those issues. The Council observed that usage of high-cost drugs and drug shortages have similar effects, and that some of the strategies used to manage drug

shortages could be applied to managing use of high-cost drugs. The Council discussed strategies and made the following recommendations.

Management or Director Actionable Items

- Creation of a shortage/high-cost subcommittee as a component of pharmacy and therapeutic committees (this could be the subject of ASHP policy).
- Allocation of time and resources for more frequent medication-use evaluations for classes of medications on formulary when formulary items increase in price.
- Exploring reimbursement models that favor outpatient dispensing as a cost-saving measure.
- Creation of a high-cost drug policy or standards on managing high-cost drugs.

Clinical Decision-making

- Creation and maintenance of internal anticipatory recommendations for major drug classes would be ideal.
- Working with informatics pharmacists and licensed practitioners to develop temporary restriction protocols that trigger pharmacist consults on high-cost drugs.
- Transition of care upon discharge.
- Optimizing dosing, route, and frequency of administration for high-cost drugs with licensed practitioners.

Informatics

- Leveraging technology to assist in identifying changes in drug prices, alerting responsible clinical and management parties, as early identification is important.
- De-identifying resolved pricing issues is also important.

General Recommendations

- Creation of a toolkit of strategies or best practices for mitigating high-cost drug prices through informatics, clinical decision-making, and management strategies.
- Advocate for ethical and equal distribution of medications, as some patients have not been able to obtain a drug because their institution is not in the correct tier to receive a certain drug product.
- Creation of a community or forum that addresses decreasing waste, encourages transparent and collaborative efforts to assist in therapeutic change recommendations, ethical considerations, and post-marketing surveillance.
- Engaging leaders in the field to raise awareness of the impact of high drug costs through ASHP communication tools such as *AJHP* editorials and ASHP Connect blogs.
- Creation of education on the basics of formulary management as well as informatics best practice on management of shortages and high-cost drugs.

2017 Report of the ASHP Treasurer

Appendix V

Am J Health-Syst Pharm. 2017; 74:
1283-5

**Thomas J. Johnson, Pharm.D.,
M.B.A., BCCCP, BCPS, FASHP, FCCM,**
Treasurer, Avera McKennan Hospital,
Sioux Falls, SD.

Address correspondence to
Dr. Johnson (thomas.johnson@avera.org).

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ASHP continues to be a strong and vibrant
organization from both a membership
and financial viewpoint.



Each year, the Treasurer has the responsibility to report to the membership on ASHP's financial condition. ASHP's fiscal year is from June 1 through May 31, coinciding with our policy development process and timetable. This report describes ASHP's financial performance and planning for three periods, providing (1) the final audited numbers for fiscal year 2016 (prior year), (2) the projected performance for fiscal year 2017 (current year), and (3) the budget for the fiscal year 2018, ending May 31, 2018.

ASHP segregates its finances into two primary budgets, core operations and the program development budget. The core operations budget represents the revenue and expense associated with the operations of ongoing ASHP products, programs, and services, as well as infrastructure support. The program development budget is intended for expenditures that are (1) associated with new, enhanced, and expanded programs; (2) associated with time-limited programs; (3) capital asset purchases; or (4) supplemental operating expenses. The program development budget is funded primarily with investment income. Because of ASHP's strong financial base and the sale of ASHP's

building in May 2016, there are three additional funding sources. The first is reserves/net assets. Funding programs from reserves/net assets is only occasionally used. These programs are reviewed on a case-by-case basis and approved by the Board of Directors. The second is the Building Fund. The Building Fund was created to hold the net gain from the sale of ASHP's building so that the investment earnings can be used to pay for lease and other occupancy-related expenses associated with ASHP's new offices. The third additional funding source is the Building Sale Reserve Funds. The Building Sale Reserve Funds were funded by a portion of the cash proceeds from the sale of ASHP's building, and the investment earnings are intended to be used for new programs, products, and services, as well as to sustain ASHP through an economic downturn.

The fiscal year 2016 financial audit of ASHP and its subsidiary, the 7272 Wisconsin Building Corp., for fiscal year 2016 ending May 31, 2016, was performed by the independent audit firm of Tate & Tryon. The audit resulted in ASHP receiving the best opinion available, an unmodified opinion.

Fiscal Year Ending May 31, 2016—Actual

ASHP's core operations had another successful year, with a \$305,000 surplus, and program development had

a deficit of \$1.36 million due to lower-than-budgeted investment income (Figure 1). Spending from reserves/net assets was \$155,000, and we had a favorable pension adjustment of \$1.451 million. ASHP's net assets at May 31, 2016, represented 71%¹ of total fiscal year 2016 expense. Our long-term financial policy is to maintain reserves/net assets at a target of 70% of total ASHP and 7272 Wisconsin Building Corp. expenses.

As was noted in last year's Treasurer's Report, ASHP was in negotiations to sell its headquarters building. I am pleased to report that our headquarters building was sold on May 26, 2016. The Board of Directors' decision to sell our building was clearly in the members' best strategic and financial interests. In anticipation of the sale of ASHP's headquarters building, the Building Fund was established to hold the net gain from the building sale. The Building Fund was designed, over the long term, to provide investment returns that would at least replace the income previously generated from leased commercial and office space at 7272 Wisconsin Avenue, and to pay for lease and other occupancy-related expenses associated with ASHP's new offices.

ASHP's May 31, 2016, year-end balance sheet (Figure 2) remained impressive. The May 31, 2016, asset-to-liability ratio stood at 5.98:1.

Fiscal Year Ending May 31, 2017—Projected

As of February 28, 2017, the financial performance from core operations, program development, and reserves/net assets for the fiscal year ending May 31, 2017, is projected to produce net income of \$338,000 (Figure 1). If the financial markets continue to show favorable returns, we anticipate the Building Fund and Building Sale Reserve Funds will show

a total surplus of \$1.1 million at fiscal year-end. Projections do not include any potential pension adjustments.

Fiscal Year Ending May 31, 2018—Budgeted

ASHP's fiscal year 2018 core operations and program development budgets are balanced, with a combined \$1,000 surplus (Figure 1). We are pleased to continue to keep ASHP's total dues revenue at a low 12% of

total core revenue. Reserves/net assets spending is budgeted at \$714,000 for additional enhancements and depreciation expense for ASHP's new website and for investing in the development of certification programs content for newly approved BPS specialties. Although this spending will cause an overall deficit for fiscal year 2018, ASHP's total reserves/net assets are still budgeted to be at a strong 70% of total fiscal year 2018 expense.

Figure 1. ASHP condensed statement of activities (in thousands).

	Actual Fiscal Year Ended 31-May-16	Projected Fiscal Year Ended 31-May-17	Budget Fiscal Year Ended 31-May-18
CORE OPERATIONS			
Gross revenue	\$46,655	\$48,760	\$50,712
Total expense	(49,013)	(48,573)	(50,861)
Earnings from 7272 Wisconsin Building Corp.	2,663	0	0
Investment income subsidy	0	150	150
Core Net Income	\$305	\$337	\$1
PROGRAM DEVELOPMENT			
Investment income	(\$171)	\$1,272	\$1,377
Program revenue	222	300	567
Program expenses	(1,411)	(1,238)	(1,944)
Program Development Net Income	(\$1,360)	\$334	\$0
Programs Funded from Reserves/Net Assets	(\$155)	(\$333)	(\$714)
Increase in Reserves/Net Assets	(\$1,210)	\$338	(\$713)
Pension Plan Adjustment	1,451	—	—
Net Increase in Reserves/Net Assets	\$241	\$338	(\$713)
BUILDING FUND			
Investment income	\$79	\$3,895	\$4,209
Gain on sale of building	86,027		
Building expenses	(113)	(2,967)	(4,976)
Building Fund Net Income	\$85,993	\$928	(\$767)
BUILDING SALE RESERVE FUNDS			
Investment income	\$0	\$134	\$810
Building expenses	0	0	0
Building Sale Reserve Funds Net Income	\$0	\$134	\$810

Figure 2. ASHP statement of financial position (in thousands).

	Actual as of 31-May-16	Actual as of 31-May-15
ASSETS		
Current assets	\$5,449	\$4,051
Fixed assets	\$329	\$597
Long-term investments (at market)	\$136,638	\$34,668
Investment in 7272 Wisconsin Building Corp.	\$5,642	\$21,730
Other assets	\$269	\$249
Total Assets	\$148,327	\$61,295
LIABILITIES		
Current liabilities	\$18,061	\$16,548
Long-term liabilities	\$6,746	\$7,462
Total Liabilities	\$24,807	\$24,010
RESERVES/NET ASSETS		
Net assets*	\$123,520	\$37,285
Total Net Assets	\$123,520	\$37,285
Total Liabilities and Net Assets	\$148,327	\$61,295

*Includes \$86M net gain from the sale of ASHP's building on May 26, 2016. The investment earnings from these monies are designated to pay lease and other occupancy-related expenses for ASHP's new offices.

With respect to the Building Fund and Building Sale Reserve Funds, together they are budgeted to generate a surplus of \$43,000.

7272 Wisconsin Building Corporation

ASHP's subsidiary, the 7272 Wisconsin Building Corp., owned the ASHP headquarters building and derived income from leased commercial and office space. With the sale of ASHP's building on May 26, 2016, this subsid-

iary is in the process of being closed down in an orderly manner.

Conclusion

This is my first report to the House of Delegates and membership and I am honored to serve as your Treasurer. I am very pleased to be a part of a progressive Board of Directors that is committed to supporting and advancing the profession of pharmacy in hospitals and health systems. ASHP continues to be a strong and vibrant

organization from both a membership and financial viewpoint. ASHP's strong financial resources, highly engaged membership and Board, and outstanding CEO and staff have us all positioned to meet the current and future needs of our profession.

¹The Building Fund and the Building Sale Reserve Funds are excluded from the reserves/net assets calculation due to their designated use.

2017 REPORT OF THE PRESIDENT AND CHAIR OF THE BOARD

Appendix VI

ASHP's journey to discovering pharmacy's true north

Am J Health-Syst Pharm. 2017; 74:1271-4

Lisa M. Gersema, Pharm.D., M.H.A., BCPS, FASHP, United Hospital, St. Paul, MN.

Address correspondence to Dr. Gersema (lisa.gersema@allina.com).

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As pharmacists, we must demonstrate excellence in our practice and our medication knowledge that is second to none.



It is hard for me to believe that it has been a year since I was installed as ASHP's president. I still recall sitting at the Whitney dinner when it hit me—wow, I am president of ASHP—what an honor and privilege I have just been given. Thus began one of the most exceptional years of my professional career.

I cannot begin to thank all of my colleagues and friends who supported and encouraged me during the past year. I especially appreciate my United Hospital and Allina-Health colleagues who accepted additional responsibilities and work so I could serve as ASHP's president. I will be forever grateful for their support and understanding.

Harry Truman once said, "It is amazing what you can accomplish if you do not care who gets the credit." He could have been talking about ASHP when he said this. There are so many outstanding and unselfish ASHP members participating in numerous ways while working in concert with an exceptionally talented ASHP staff toward a common purpose—to advance our profession and to support the best possible healthcare and

medication management for the patients we serve.

As president, I have been afforded the unique opportunity to witness just how incredible ASHP is! I have gained insight into the many accomplishments of ASHP and witnessed the tremendous impact it has on our profession of pharmacy, which allowed me to appreciate the exceptional organization that it is.

I want to thank you, as members of the House of Delegates, for the time you have committed to ensure that ASHP policies meet the needs of members, patients, and pharmacy practice. The work of the House of Delegates, along with that of ASHP's Councils, Sections, Forums, and state affiliates, is a testament to the unwavering commitment of ASHP members to optimize medication use, expand pharmacists' roles, and improve patient care.

I would also like to recognize the dedication of the ASHP Board of Directors. Thank you for your commitment, your leadership, and your passion. This sets the stage for us to support ASHP's mission to help people achieve optimal health outcomes.

On behalf of the Board of Directors, I want to thank our chief executive officer, Paul Abramowitz, for his encouragement and guidance throughout the

year. Paul has done an exceptional job of leading ASHP through an exciting time of growth and change—the sale of our former headquarters at 7272 Wisconsin Avenue, the relocation to our new state-of-the-art offices in the Joseph A. Oddis Global Headquarters of ASHP, growing membership and revenue, and so much more. Thank you, Paul.

In my inaugural address, I introduced the concept of pharmacy's true north, which comprises 4 critical attributes—accountability, collaboration, excellence, and leadership. My professional journey as ASHP's president only served to strengthen the importance of these points for me. Today, I would like to share just a few of the ASHP programs, activities, and accomplishments that contribute to a successful journey as we find our true north.

Accountability

The cornerstone of pharmacy's true north is accountability. As pharmacists, we must accept accountability for patient's medication-related outcomes and be accountable to our professional colleagues with whom we collaborate to optimize the care of our patients.

ASHP is accountable to its members to provide the tools and support

needed by pharmacists to help patients reach their therapeutic goals. An example of this is ASHP's Practice Advancement Initiative, or PAI—formerly called the Pharmacy Practice Model Initiative.

The PAI blends the goals identified during the Pharmacy Practice Model Summit and the Ambulatory Care Summit into one initiative that empowers pharmacists to take accountability for patient outcomes in acute and ambulatory care settings.

The PAI provides tools and resources to guide and support practitioners and pharmacy leaders as they advance pharmacy practice. New offerings in 2017 include made-to-order gap analysis tools and guidance that will assist individual practitioners, healthcare organizations, and state affiliates to focus their priorities for improvement.

As of today, more than 1,700 hospitals have completed the Hospital Self-Assessment, and more than 470 ambulatory care sites have taken self-assessments. ASHP continues to support members in a variety of PAI activities, including providing speakers, custom self-assessment reports, and guidance on how to implement improvements.

In 2016, the ASHP Research and Education Foundation funded 6 state affiliate grants to support PAI planning and implementation. This year, PAI grant workshops are scheduled in Iowa, South Carolina, and Florida.

The workshops and grants have been incredibly successful! For example, participants established discharge and admission medication reconciliation pilot programs, added advanced technician roles, and provided education about current reimbursement practices.

ASHP's Sections and Forums provide many different ways for members to engage in ASHP. In the past year, ASHP's Sections provided opportunities for more than 900 members to volunteer with advisory groups and committees—that equals an astounding 10,000 hours of volunteer time!

At the Midyear Clinical Meeting in Las Vegas, at last year's Summer Meetings, and at the ASHP Leadership Conference, Sections conducted 46 networking sessions. More than 5000 ASHP members participated in these important, engaging events, which were facilitated by member volunteers.

Collaboration

The second construct of pharmacy's true north is collaboration. My year as president of ASHP has shown me that pharmacists have more opportunities to collaborate than ever before.

Nowhere is the idea of collaboration more evident than in our professionwide pursuit of provider status. The Pharmacy and Medically Under-served Areas Enhancement Act was reintroduced on January 20, 2017. The legislation now has 175 cosponsors in the House and 39 cosponsors in the Senate. ASHP staff and members have taken a leadership role to advance this legislation through Congress. I witnessed firsthand how tirelessly our members came together to share their stories with legislators to demonstrate the valuable services that we provide as pharmacists.

In February of this year, the Pharmacy Technician Certification Board sponsored a stakeholder consensus conference to address unsettled issues related to pharmacy technicians. This conference was planned in collaboration with ASHP and the Accreditation Council for Pharmacy Education. Eighty-nine participants from many different pharmacy practice types and professional organizations representing various viewpoints on this important issue were invited to participate. The work completed at this conference identified many important recommendations regarding definition, entry-level requirements, advanced practice, certification, and regulation of pharmacy technicians. The proceedings of this conference will be published online later this month and in print in the September 1, 2017, issue of *AJHP*.

Another outstanding example of collaboration is the relationship between ASHP and our state affiliates. ASHP affiliate organization members help ASHP move the profession forward at the state level. This past year, ASHP board members spoke at 13 state affiliate meetings, and ASHP staff attended 23 state affiliate meetings. ASHP Chief Executive Officer Paul Abramowitz was the keynote speaker at 5 affiliate meetings.

Over the past year, ASHP has worked with the Institute for Safe Medication Practices to create the Medication Safety Certificate Program, which was rolled out last month. This self-guided, online continuing-education program, which comprises 16 modules, provides pharmacists, physicians, nurses, and other healthcare professionals with the essential skills for improving the safety of medication use in their respective practice settings.

As you all know, the opioid epidemic is a health crisis that affects communities in every state. ASHP is collaborating with the National Governors Association to devise strategies to address the opioid epidemic to ensure a coordinated response across all levels of government. Pharmacists play a critical role in preventing inappropriate prescribing, misuse, and abuse of opioids, as well as counseling patients and family members about the symptoms of overdose.

Excellence

The third construct of pharmacy's true north is excellence. As pharmacists, we must demonstrate excellence in our practice and our medication knowledge that is second to none. We must be confident and skilled enough to demonstrate our clinical excellence to other healthcare providers.

In 2016, ASHP launched the first of 3 online professional certificate programs to help pharmacists and pharmacy technicians improve patient care. Two additional programs, the Advanced Sterile Product Preparation and Training Program and the Medi-

cation Safety Certificate Program, were launched in 2017.

ASHP continues its commitment to support members in their pursuit of clinical excellence by offering board certification review courses and recertification programs for oncology, ambulatory care, pharmacotherapy, pediatrics, critical care, and geriatrics. I am pleased to announce that the ASHP Board of Directors recently approved funding for ASHP staff to pursue development of preparatory courses for the 2 newest specialties—cardiology and infectious diseases.

ASHP truly shines when it comes to excellence in residency education and training. In recent years, the number of pharmacy students participating in the Match has grown exponentially. Over the past 5 years, the number of residency positions has increased by 1,224 positions, or 36%. This is confirmation of our members' commitment to building residency program capacity. Thank you for all of your efforts in this area.

This is the second year that ASHP has offered a 2-phase Match program, which gives applicants who did not match during phase 1 another opportunity to match with a residency program. As the program director for the postgraduate year 1 program at United Hospital, I was given the opportunity to participate in phase 2 of this year's Match. I admit I was a bit distressed when I discovered that we had a vacancy to fill, but my anxiety quickly dissipated as I began to review the truly incredible applications that I received for that vacancy. The process for phase 2 of the Match was outstanding, and I am extremely pleased with our outcome.

ASHP is well respected for the excellent quality of its professional meetings. This is reflected by continuous growth in attendance at the Summer Meetings and the Midyear Clinical Meeting. We continue to experience growth in the number of participants in the Residency Showcase, the Personnel Placement Service, and poster submissions. The total attendance for

last year's Summer Meetings was the highest it has been since 2009. The 2016 Midyear meeting in Las Vegas was remarkably successful, with more than 25,000 attendees.

The Midyear Clinical Meeting is recognized as the largest professional gathering of pharmacists in the world. Its continued growth in the number of attendees has captured the attention of others outside of pharmacy. ASHP received several awards for the success of the 2016 Midyear meeting. These include the Trade Show Executive Fastest 50 and TSE Fast Tracker awarded by *Trade Show Executive*. In addition, Trade Show News Network listed the ASHP Midyear meeting on its "Top 250 Trade Shows of 2016" list.

The Washington Post recognized ASHP for excellence by naming us as 1 of the 2016 Top Workplaces in the Washington, D.C., area. Top Workplaces are chosen based on confidential employee engagement surveys. More than 90% of ASHP staff members participated in the survey, and the results demonstrated that ASHP staff have a remarkably high level of employee engagement.

Last month, ASHP was among 150 companies and organizations named to *Modern Healthcare's* Best Places to Work in Healthcare in 2017. This honor is based on an organization's policies, practices, benefits, and demographics and an extensive staff engagement survey. This nationwide recognition by *Modern Healthcare* further shows how remarkable ASHP members and staff are. Congratulations to Paul and his staff for these recognitions, and thank you for the exceptional job you do in supporting ASHP's nearly 45,000 members.

Leadership

So far, I have talked about how my year as ASHP's president further shaped my understanding of accountability, collaboration, and excellence. The fourth construct of pharmacy's true north is leadership. This is a true strength of ASHP, and one that is rec-

ognized not only by its members but by others outside of ASHP.

There are many examples where ASHP has demonstrated leadership in the profession, and I'd like to take a moment to highlight just a few.

This year ASHP released 2 new publications. *The Effective Pharmacy Preceptor*, written by Mate M. Soric, Stacey R. Schneider, and S. Scott Wisneski, is a new reference to help pharmacists train students and residents for their patient care roles. ASHP also published *The Chapter <800> Answer Book* by Patricia Kienle, which is a comprehensive guide to every area of compounding, administering, storing, and disposing of hazardous drugs.

Last year, ASHP launched the Standardize 4 Safety initiative, the first national, interprofessional effort to standardize medication concentrations in order to reduce errors and improve transitions of care. Since the launch, we have finalized the list of recommended concentrations for adult i.v. continuous infusions, and we are now seeking comments on concentrations for compounded oral liquids.

In January, ASHP published the first-ever national guidelines on best strategies to monitor and prevent controlled substances drug diversion. These guidelines establish the framework for a collaborative and comprehensive program to protect patients, employees, and organizations from the risks of controlled substances drug diversion. The guidelines were quickly and effectively developed in response to member concerns about the lack of published national guidelines in this area. The member work group and ASHP staff who developed these guidelines are to be commended for their focus and timely response to this rapidly growing national issue. ASHP has quickly continued to support members following this publication with a series of webinars reaching thousands of members, including programming here at the Summer Meetings. ASHP will continue to have controlled substances management

and the opioid crisis as top advocacy and education priorities.

Last fall, the ASHP Board of Directors received and approved the report from the Women in Pharmacy Leadership Steering Committee. This report acknowledges the changing demographics of pharmacy and addresses the needs and opportunities for leadership development at several levels, regardless of gender. The report includes guidance statements to ASHP, those seeking leadership positions, current leaders, and employer organizations and pharmacy departments. ASHP promotes the Women in Pharmacy Leadership initiative through podcast series, networking sessions at ASHP meetings, the Connect community, and a special series of articles in our online publication, *InterSections*.

Conclusion

As my year as president of ASHP comes to a close, I encourage every one of you to focus on your true north. Accept accountability for patient outcomes and strive to expand pharmacy's role at your organization. Collaborate with members of your healthcare team and move beyond a pharmacy-centric perspective. Demonstrate your commitment to excellence by taking advantage of ASHP's exceptional continuous professional development opportunities. And finally, seek opportunities to lead the medication-use and patient care initiatives within your practice setting.

ASHP celebrates its 75th anniversary this year, and I am extremely proud of all of the work ASHP has done to advance the practice of pharmacy to where it is today. ASHP has

always been an organization with an eye toward the future, and it is my hope that we continue to build upon our past accomplishments to achieve even greater success in the future by helping patients have access to the services that pharmacists provide.

We couldn't have gotten this far without the tireless efforts of our dedicated members. Thank you for all that you do for your patients, your colleagues, and ASHP. It has been an absolute pleasure to serve as your president. Thank you.

Disclosures

The author has declared no potential conflicts of interest.

Additional information

Presented at the ASHP Summer Meetings, Minneapolis, MN, June 6, 2017.

2017 REPORT OF THE CHIEF EXECUTIVE OFFICER

Appendix VII

ASHP: 75 years of leadership, innovation, and growth

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Paul W. Abramowitz, Pharm.D., Sc.D. (Hon), FASHP, ASHP, Bethesda, MD.

Address correspondence to Dr. Abramowitz (ceo@ashp.org).

Keywords: leadership, pharmacy, innovation, residency training, patient care, drug cost

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History will ultimately be the judge of what ASHP has accomplished over its first 75 years, but I believe we have made remarkable progress and have set a great course for the next 75 years.



I would like to welcome and thank all of you as delegates for your time, dedication, and yearlong efforts to ASHP and our profession. The theme of my comments today is 75 years of leadership, innovation, and growth. I would like to assure you that the state of pharmacy practice and ASHP is strong, and the future is bright.

As we celebrate ASHP's 75th anniversary, the vision for pharmacy

as a patient care-focused profession has come to fruition and is growing by the day. Further, it's because of you, our members, that ASHP and our profession are on a path to ensure that every patient has access to a pharmacist to optimize his or her health through the appropriate use of medications.

This year marks ASHP's 75th anniversary. ASHP was a much smaller organization in its early years but has remained the leader that others follow because of the vision of individuals like Gloria and Don Francke,

Harvey Whitney, Joseph Oddis, Henri Manasse, and many other dedicated volunteer leaders and staff members. ASHP has led the way on countless issues, such as the conceptualization and advancement of clinical pharmacy, access to the patient care services of pharmacists, residency training, medication safety, drug information, and the vital role of pharmacy technicians. These are just a few of the many examples of ASHP's proactive leadership over the past 75 years.

Before I move on with my remarks, I would like to take a moment to recognize ASHP's wonderful staff of over 200 professionals who work every day to support our nearly 45,000 members and the patients they serve. I also would like to recognize the outstanding efforts of our president, Lisa Gersema. Lisa, you've been an inspiration and pleasure to work with and, of course, have done an exceptional job.

Likewise, I would like to recognize and thank the ASHP Board of Directors. This amazing group of people is focused on creating a future that ensures that pharmacists are the medication therapy experts and are present on all patient care teams. The Board works so incredibly hard to advance ASHP's membership and public



Photo courtesy of ASHP Archives.

Gloria N. Francke



Photo courtesy of ASHP Archives.

Harvey A. K. Whitney

health mission. I consider myself very fortunate to serve as the chief executive officer of ASHP and to work with such a talented and committed group of people. Lastly, I would like to recognize our past presidents who have contributed so much to our profession and continue to do so.

I now would like to spend a few minutes talking with you about how your professional organization, ASHP, has evolved and grown over the past several years. I would like to point out upfront that this tremendous growth and evolution have resulted from the collective effort of our Board, staff, and all of you, who have a long history of being leaders in pushing the envelope to advance pharmacy practice in the interest of improving the lives of the patients we serve.

ASHP's lifeblood resides with our members. That's why I am so pleased to report that membership has experienced significant growth over the past 5 years. We've gone from 39,000 members in 2011 to more than 44,000 members today (Figure 1). Not only is total membership growing, but it is expanding in areas such as clinical specialists, ambulatory care pharmacists, and new practitioners. This growth is really no surprise, since ASHP was an early leader in describing and advancing pharmacy as a clinical, patient-oriented profession and in advancing the roles of pharmacists as direct patient care

providers in ambulatory care clinics and other outpatient settings. Today we are seeing a growing interest in ASHP by all pharmacists who provide direct patient care services, especially with the growing focus on population health and as hospitals and health systems become more and more integrated with the community and the entire continuum of patient care. Today, it is really about how pharmacists practice versus where they practice. If a pharmacist is focused first and foremost on achieving optimal outcomes for patients, then he or she should consider ASHP as his or her home. It's so amazing to see ASHP's evolution from an organization that, 75 years ago, represented only hospital-based pharmacists to one that now represents pharmacists working across the full spectrum of care.

Another important area that improves the lives of patients, and in which ASHP has grown, is residency accreditation. In just 5 years, available residency positions have in-

creased from approximately 3,400 to 4,600, and we believe that there is still considerable room for growth, given the increasing demand for residency-trained pharmacists (Figure 2). ASHP has been accrediting pharmacy residencies since 1962. This was clearly among the most important decisions that began the transformation of pharmacy into a clinical profession. When ASHP started accrediting residencies, it was a free service for nearly 5 years, after which modest accreditation fees began being assessed. For over 30 years, ASHP financially subsidized residency accreditation because it was the right thing to do for our members and their patients. Today, residency accreditation



Photo courtesy of ASHP Archives.

Joseph A. Oddis and Henri R. Manasse



Photo courtesy of ASHP Archives.

Members of the Hospital Pharmacy Subsection of the American Pharmaceutical Association at the 1942 APhA Annual Meeting in Denver.



ASHP staff members at the 2016 ASHP Midyear Clinical Meeting in Las Vegas.

is self-supporting, and our profession and patients have all benefited greatly from pharmacists with advanced postgraduate training. Pharmacy students' interest in residencies continues to grow, and we are confident that we will meet our 2020 goal of completion of a residency as a requirement for all new graduates providing direct patient care.

Another major milestone for ASHP and the advancement of clinical pharmacy practice was the creation of the ASHP Midyear Clinical Meeting over 50 years ago. The Midyear meeting was the first of its kind—a meeting that focused primarily on clinical pharmacy practice and brought pharmacists together from around the world. Over the past 5 years, the Midyear meeting has continued to exceed expectations in both content and attendance. In 2011 we had nearly 19,700 attendees in Las Vegas, and in 2016 there were 25,500 attendees, which far exceeded all expectations and previous records (Figure 3). There's nothing else in pharmacy like it in the world. The Midyear meeting is where pharmacists come to advance their knowledge, network, find a job or residency, hear top-tier speakers, and obtain continuing education.

It's the best pharmacy event around, and we plan to continue finding innovative ways to keep it that way. Regarding top-tier speakers, I hope you will be able to attend the December Midyear meeting in Orlando, where we will be honored to have as our keynote speaker former First Lady Michelle Obama!

Today, because of the efforts of ASHP, its members, and its coalition partners in the Campaign for Sustainable Drug Pricing, Congress and the White House have begun seriously exploring legislative options to address drug costs.

This positive growth at ASHP has provided us the ability to better expand our member services and better support you. Over the past 5 years, total revenues have grown from \$40.5 million to a projected \$48.5 million in fiscal year 2017 and a budgeted revenue for 2018 of \$50.7 million (Figure 4). This growth has allowed us to enhance our outreach to Congress and other stakeholders, provide board certification and

recertification resources, and offer certificate programs.

It has also allowed us to launch the Women in Pharmacy Leadership Initiative, enhance and redesign *AJHP*, launch the *AJHP Residents Edition*, and further expand our Practice Advancement Initiative. Our strong revenue also provides us with strong reserves to protect us during periods of financial downturn.

ASHP is always seeking ways to increase nondues revenue to support our membership mission. We launched ASHP International as well as international residency accreditation not only with the purpose of enhancing pharmacy practice in other nations but also to help support our U.S.-based membership mission. All net revenue from ASHP International directly supports ASHP's robust and growing member services in the United States.

The launch of ASHP International recognizes that we live in a global economy, that there are numerous opportunities to learn from other cultures and societies, and that we can work together to support mutual interests to improve patient care and advance pharmacy practice around the world.

Another major milestone for ASHP was this year's sale of ASHP's

headquarters, the Joseph A. Oddis Building. After several years of due diligence, ASHP made the decision to sell our building to a local developer to help make way for a new light-rail system and further develop downtown Bethesda. Our decision to sell was based solely on the best interests of our members and the long-term viability of ASHP.

I am extremely pleased to say that because of the sale of our building, we are in an even better position to support our members long into the future. We have now moved into a beautiful modern new space just a few blocks away from our old building, providing our exceptional staff with modern amenities to enhance their productivity and satisfaction. Our new offices, the Joseph A. Oddis Global Headquarters of ASHP, also allow us to hold

Figure 1. Growth in ASHP membership from 2011 through 2016.

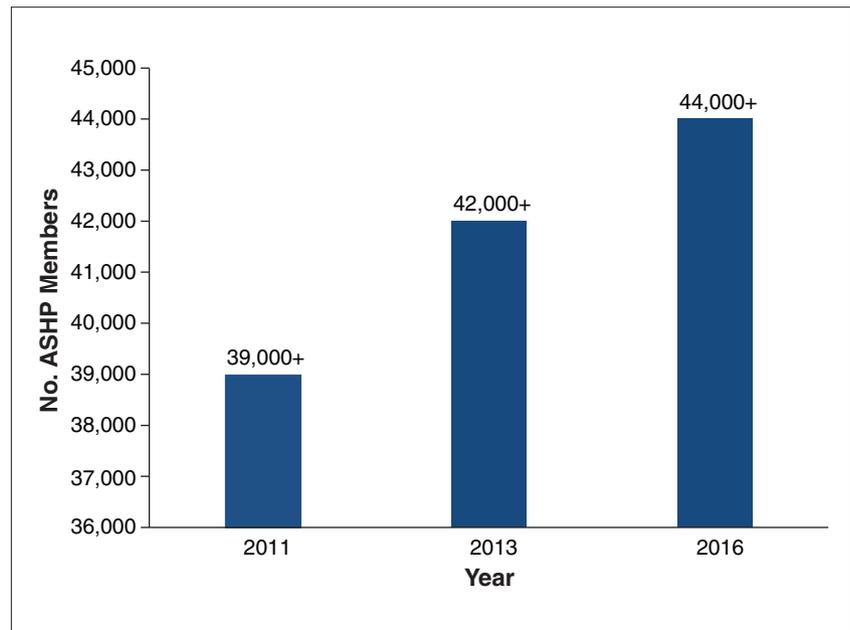
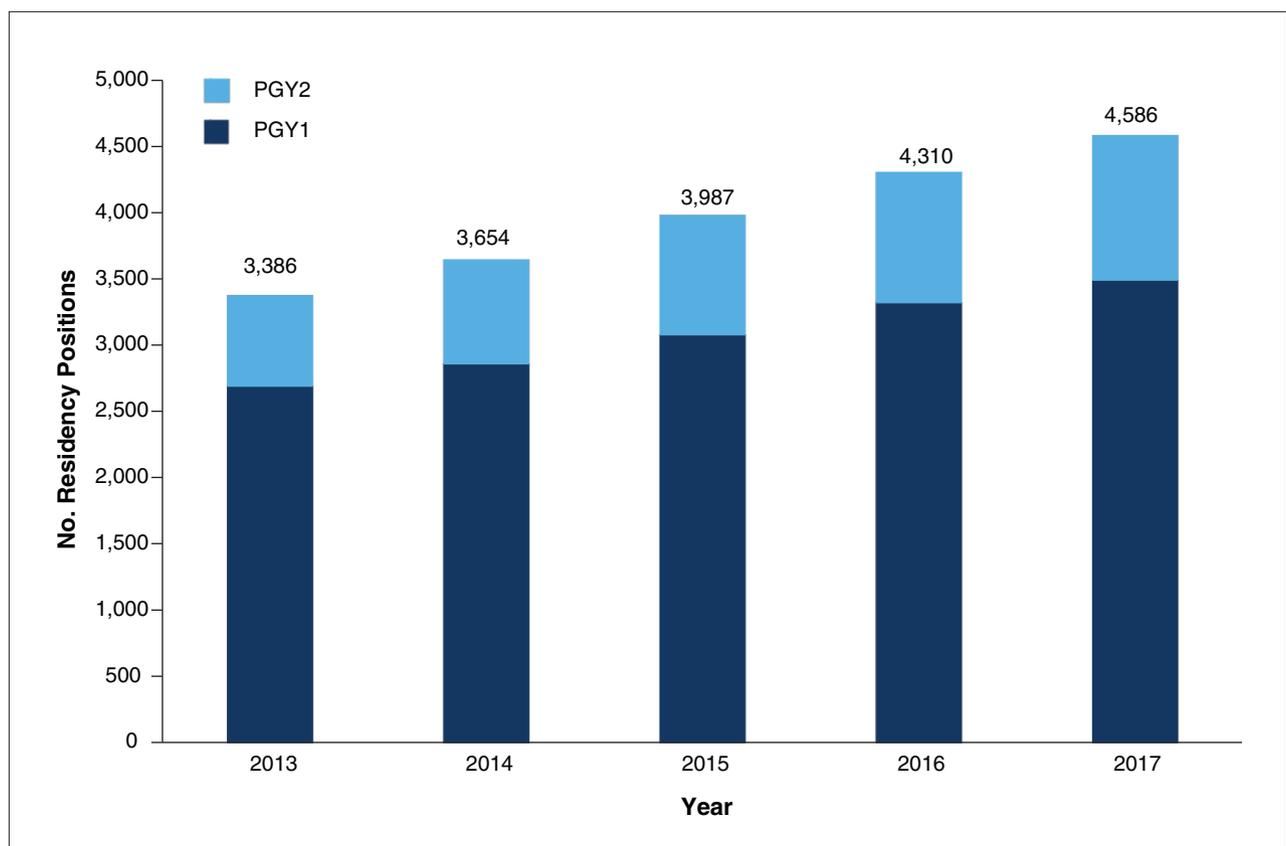


Figure 2. Growth in the number of ASHP accredited residency positions from 2013 through 2017. PGY1 = postgraduate year 1, PGY2 = postgraduate year 2.



events with members and others to help us further advance our mission.

The new space is symbolic of where ASHP is going in the future. I hope that all of you and other mem-

bers who visit the Washington, D.C., area will come visit us in pharmacy's new home.

ASHP continues to become a much more influential organization in the

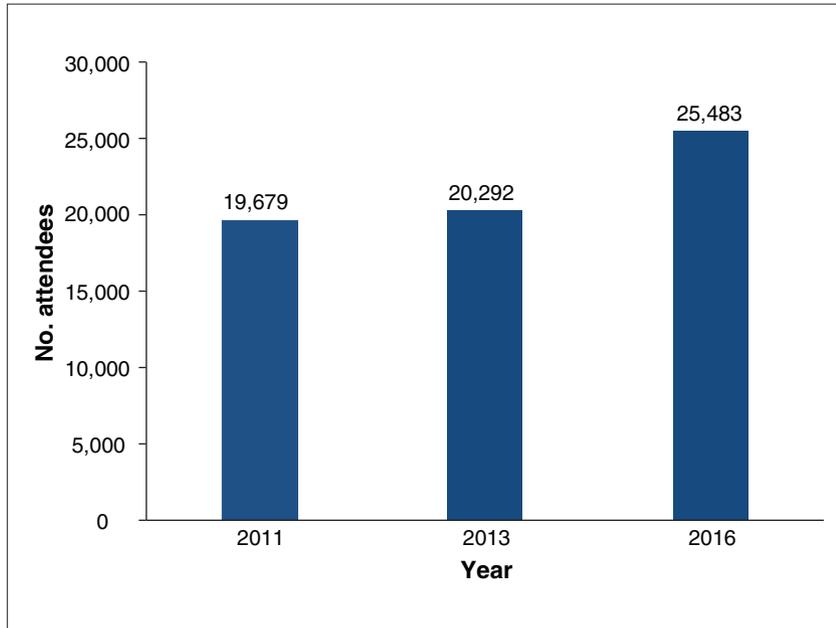
halls of Congress, among federal agencies, and with other organizations.

ASHP was instrumental in the passage of federal legislation on drug shortages and pharmacy compounding and is now pushing hard to get pharmacists recognized as Medicare providers in the Social Security Act.

ASHP was also an early leader in sounding the alarm about the impact of rapidly escalating drug prices on our patients, healthcare organizations, and our country as a whole. Today, because of the efforts of ASHP, its members, and its coalition partners in the Campaign for Sustainable Drug Pricing, Congress and the White House have begun seriously exploring legislative options to address drug costs.

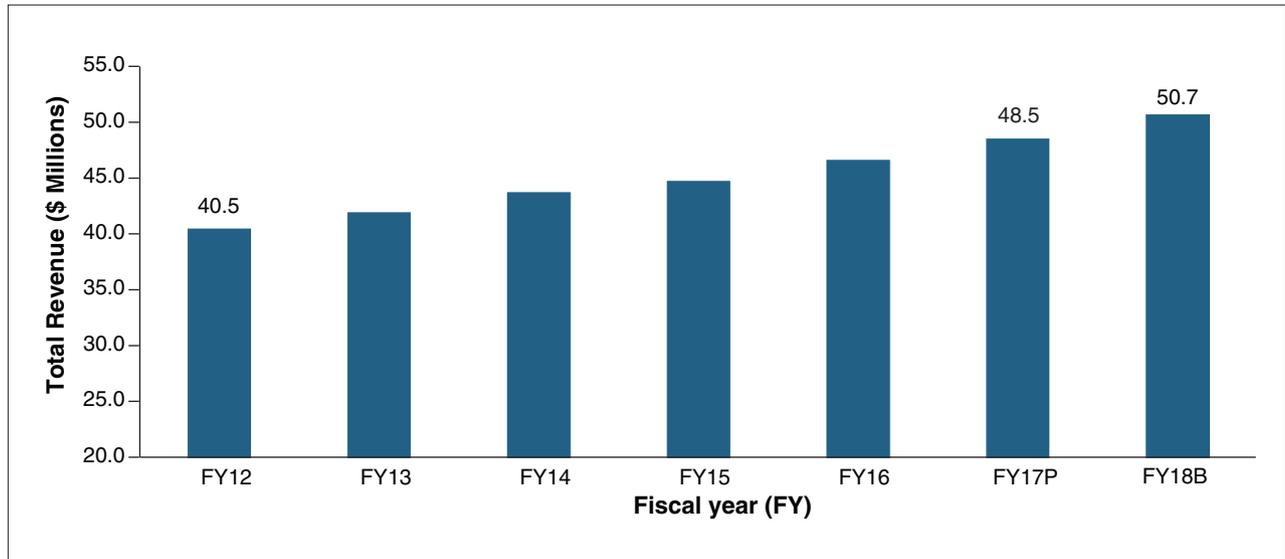
The ASHP political action committee has also grown, allowing us to support more members of Congress who support your interests and those of your patients (Figure 5). ASHP has also increased its efforts to build relationships and partner with other professional associations in medicine, nursing, healthcare administration, and

Figure 3. Growth in attendance at the ASHP Midyear Clinical Meeting from 2011 through 2016.



Joseph A. Oddis Global Headquarters Dedication Ceremony. From left, Paul W. Abramowitz, Joseph M. Oddis, Joseph A. Oddis, Marie Newman, Rebecca Newman, Debra Oddis, Richard Newman, and Lisa M. Gersema.

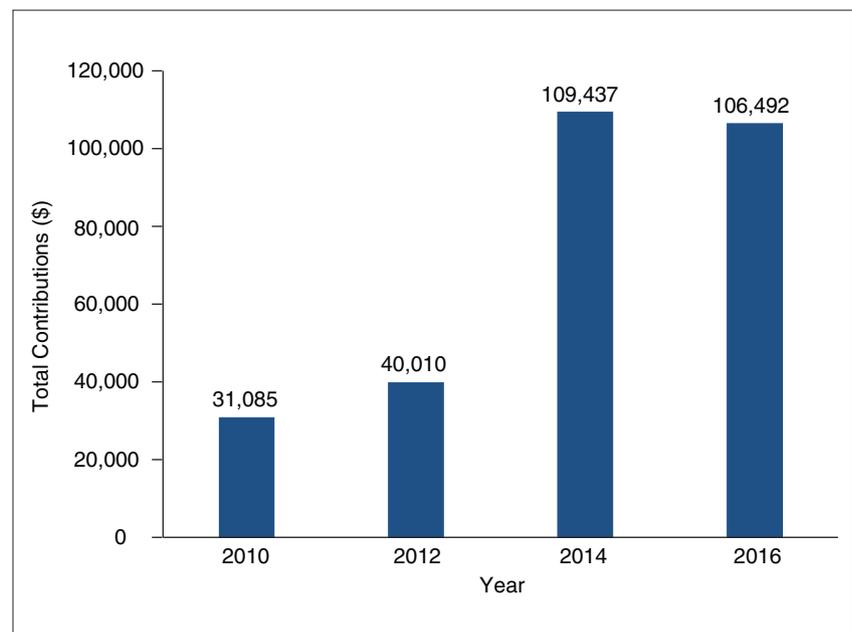
Figure 4. Growth in ASHP's total revenue from fiscal year 2012 through fiscal year 2018. The amounts listed for fiscal year 2017 and fiscal year 2018 are projected and budgeted revenue, respectively.



patient groups. We strongly believe that partnerships lead to understanding and trust, and we are working hard to make sure that the leaders in key national associations understand the vital roles pharmacists play as direct patient care providers.

I will close my comments today where I started. The states of pharmacy and ASHP are strong. We are heading down a path to an increasingly bright future for the profession and our patients. I am very proud of what you, our members, and ASHP have accomplished together. We are a team, and we're the best team anywhere. When I started my pharmacy career 40 years ago, I knew pharmacy had a future, but where we stand today as a profession has far surpassed my expectations. I would venture to say that we have also surpassed the expectations of our first chief executive officer, Gloria Francke, and all of the leaders who followed. History will ultimately be the judge of what ASHP has accomplished over its first 75 years, but I believe we have made remarkable progress and have set a great course for the next 75 years. We must, however, keep our eye on a fu-

Figure 5. Contributions to ASHP political action committee from 2010 through 2016.



ture where medication use is optimal, safe, and effective for all people all of the time.

Thank you so very much for everything that you do for ASHP and the patients you serve.

Disclosures

The author has declared no potential conflicts of interest.

Additional information

Presented at the ASHP Summer Meetings, Minneapolis, MN, June 6, 2017.

House of Delegates

2017 NEW BUSINESS SUBMISSION FORM

PLEASE RETURN BY 4PM ON MONDAY, JUNE 5, TO THE
EXECUTIVE OFFICE IN ROOM 202B, MINNEAPOLIS CONVENTION CENTER

**ASHP
HOUSE OF DELEGATES
JUNE 5, 2017
MINNEAPOLIS, MINNESOTA**

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

Date Submitted: June 5, 2017

Time Submitted: 10:54 a.m.

INTRODUCED BY (NAME):

Ryan K. Roux, PharmD, MS, FASHP

SUBJECT:

Reduction of Waste from Single Dose Vials

MOTION:

To recommend the following for consideration as policy or refer to council for discussion.

To recognize a significant amount of chemically/pharmacologically active medication is wasted from single-dose vials due to limited sterility information; further

To encourage the FDA, CDC, Centers for Medicare and Medicaid Services, and US Pharmacopeial Convention to reconcile their views on vial contents and vial sharing; further,

To encourage strategies to decrease waste from single-dose vials through development of multi-dose vial presentations for currently available single-dose vials, creation of new vial sizes with appropriate for average patient doses, dose standardization, and develop standards to allow drug vial optimization (DVO) using closed-system drug transfer devices (CSTDs) where sufficient peer-reviewed literature supports each device's safety and efficacy for this purpose.

BACKGROUND:

Proposal of this policy for consideration is timely given recent language in an Omnibus bill passed in May directing CMS to study the safety, and quality concerns associated with discarded drugs that results from weight-based dosing of medicines contained in single dose vials.

SUGGESTED OUTCOMES:

In 2016, Peter Bach, et al found that \$1.8 billion in direct drug costs were wasted annually in the US from the top 20 cancer drugs sold in single-dose vials. The proportion of left over drug in single-dose vials varies between 1% and 33%, and the cost of this wasted drug is often passed on to the patient, and if not, is absorbed by the health care system. Pharmaceutical manufacturers' profits are the direct beneficiary of this wasted medication and larger than necessary vial sizes. Several recent examples demonstrate continued movement by pharmaceutical manufacturers to decrease available vial sizes and increase profits. In February 2015, Merck discontinued a 50mg presentation of pembrolizumab in the United State in favor of only a 100mg presentation, while the 50mg vial is still available in Europe. In May 2017, Genentech announced it would discontinue its 440mg multi-dose vial of trastuzumab and replace it with a 150mg SDV. The Merck change is estimated to produce \$1.2 billion in additional revenue over the next 5 years (on top of the \$1.2 billion in waste that was estimated from the 50 mg vial), and it is unknown at this time the additional revenue growth that will be generated for Genetech with its change.

In May 2017, the Hematology/Oncology Pharmacy Association (HOPA) hosted a Drug Wastage Summit and invited pharmaceutical manufacturers, CSTD manufacturers, and oncology pharmacists and practice leaders to discuss the issue of drug waste in oncology. During this Summit, several presentations were given showing the safety and efficacy of DVO by institutions, dose rounding programs, and efforts by one manufacturer to create vial sizes more appropriate for typical doses of a medication. At UNC, DVO has been practiced since 2011. It was estimated that their drug budget would be 93% higher (\$70.1 million vs. \$36.3 million) without the practice of DVO using a CSTD. Further, routine testing of vials used beyond 6 hour has shown safety of this practice in more than 1000 samples tested for microbiological contamination. In this setting, they have only found 2 positive samples, both during the first month of testing and attributed to poor sampling technique, which represents a contamination rate of 0.2%. In the example of a drug manufacturer changing the vial size, a 190mg vial size was added to the previously available 500mg presentation. This additional size reduced waste by 87.6%

Supporting Policies: 1525, 1401, 0903, 0616

House of Delegates

Recommendations from the 2017 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. **USP 800 Assessment of Risk Standardization**

Joan Kramer (KS), Richard Pacitti (PA), Christine Roussel (PA), Gregory Burger, Jesse Hogue

Recommendation: That ASHP develop and publish best practice handling standards for all hazardous medications and their accompanying assessment of risk for all available dosage forms on the NIOSH list; further, to utilize subject matter experts to offer this publication free of charge to all ASHP members.

Background: ASHP has the opportunity to lead drug safety best practices for patients and health care personnel. Small health-systems do not have the resources to work through the NIOSH list and perform a risk assessment for every dosage form. Drs. Roussel, Pacitti and Burger have examples they are willing to share to assist with this effort.

2. **Medical Surveillance of Healthcare Workers Occupationally Exposed to Hazardous Drugs on a Federal Level**

Joan Kramer (KS), Richard Pacitti (PA), Christine Roussel (PA)

Recommendation: Urge federal entities (CDC, NIOSH, etc.) to create a Medical Surveillance program on a national level to minimize adverse health effects in personnel potentially exposed to hazardous drugs, as healthcare entities are not properly equipped to detect changes; further this program could provide a structure and documentation to track exposure and for assessment of symptoms and laboratory values.

Background: Medical Surveillance as a means for secondary prevention of adverse health outcomes in potentially occupationally exposed healthcare workers “should” be a component in a comprehensive hazardous drug handling program. As with all surveillance studies, population size is critical to detection of changes, further more healthcare workers move from entity to entity and should have continuous longitudinal monitoring. A standardized survey / data collection tool would contribute to the overall body of knowledge on exposure risk.

3. **Guidance for Compounding Sterile Preparations in Short Supply**

Derek Burns (MT)

Recommendation: That ASHP create guidance for healthcare systems for compounding sterile products that are in short supply or on backorder due to national shortages.

Background: Healthcare systems across the U.S. are experiencing shortages of emergent medications. Having guidance would ensure that healthcare facilities are acting in uniformity and with accurate scientific data for compounding these medications.

4. ASHP Guidance on Long-term Stability

Carol Rollins (AZ)

Recommendation: That ASHP develop guidelines related to long-term stability of products used in home infusion therapy, particularly complex products such as chemotherapy and parenteral infusion.

Background: ASPEN guidelines are not adequate for this task.

5. Pharmacist's Role in Sleep Management

Ashley Schraber (USPHS), Renee Robinson (USPHS),
Lara Nichols (AK), Alice Moss (USN), Winnie Lok-Park (USAF), Julie Groppi (USVA), Amy Sipe (MO)

Recommendation: That ASHP review pharmacists' and pharmacy's roles in sleep management, hygiene, and proper use of medications as sleep aids and encourage education for pharmacists in these areas through an ASHP policy.

Background: A 2015 CDC article states that "sleep is increasingly recognized as important to public health, with sleep insufficiency linked to motor vehicle crashes, industrial disasters, and medical and other occupational errors." (www.cdc.gov/features/dssleep) We think there is an opportunity for pharmacists to play a role in counseling both on medications and sleep hygiene as well as be involved in sleep clinics/studies associated with their facilities.

6. Pharmacist Oversight of Medication Records

Sylvia Belford (SOPIT)

Recommendation: That ASHP promote pharmacists as the primary oversight of all medication records in health information technology systems.

Background: None

7. Pharmacy's Role in Storage, Handling, and Dispensing of Fecal Matter Transplantation Materials

Scott Anderson (VA)

Recommendation: That ASHP develop policy regarding pharmacy's role in fecal matter transplantation material storage, handling, and dispensing

Background: Fecal matter transplantation is increasing in occurrence. Pharmacy's role in fecal matter transplantation material storage, handling, and dispensing is unclear and varies among institutions. In addition, pharmacies are not equipped to properly store, handle, and dispense fecal matter.

8. Reduction of Waste from Single-Dose Vials

Jennifer Sterner Allison (GA)

Recommendation: That ASHP encourage identification and implementation of strategies to decrease waste from single-dose vials.

Background: In 2016, Peter Bach et al. found that \$1.8 billion in direct drug costs were wasted annually in the U.S. from the top 20 cancer drugs sold in single-dose vials. The proportion of leftover drug in single-dose vials varies from 1% to 33%, and the cost of this wasted drug is often passed on to the patient or absorbed by the health system.

9. Pharmacist's Role in Stem Cell Biologicals Preparation and Distribution

Kathy Baldwin (FL)

Recommendation: That ASHP define the roles of the pharmacist in preparation and distribution of stem cell biologicals.

Background: None

10. Past Chair Role on Councils

Tate Trujillo (IN), John Hertig (IN), Amy Sheehan (IN), Lisa Mascardo (IA)

Recommendation: That ASHP consider the role of past chair for ASHP councils to ensure continuity.

Background: Past chair role is not consistent with ASHP. COC utilizes a past chair and it would add value to Councils.

11. Using ASHP Policies to Educate All Health Professionals

John Hertig (IN), Tate Trujillo (IN), Amy Heck (IN)

Recommendation: ASHP should develop policy language to encourage all health professionals, and not just fellow pharmacists, to use ASHP statements, guidelines, and professional policies as an integral part of education and training.

Background: The CEWD reviewed policy 0705 as part of sunset review and added new language approved by the HOD in 2017. This language was focused on the pharmacy profession. Additional language, or new policy is needed that would apply to all health professionals.

12. Support Development of Pharmacy Resident Wellness Programs

Dave Hager (WI)

Recommendation: Additionally monitor suicide and study impact of resident duty hours.

Background: None

13. Nashville!

Casey White (TN)

Recommendation: Please place a meeting, any meeting in Nashville.

Background: Original recommendation to explore Nashville as a potential summer meeting site made in 2011. Now requesting ASHP consider Nashville as a destination for any meeting ASHP is planning including Midyear. Nashville has shown the ability to handle large groups such as this as it held NRA convention with over 70,000 attendees. The membership is ready for the Nashville Experience. And Nashville is ready for the membership. Any meeting or conference is a fantastic start to a beautiful and meaningful friendship!

14. Guidelines for Pharmacist Relations with Industry

Casey White (SCSS)

Recommendation: Request an update on the status of the Guidelines for Pharmacist Relations with Industry.

Background: None

15. Standardization of Collaborative Practice Terminology to Support Provider Status Legislation

Juliann Horne (NM), Melanie Dodd (NM)

Recommendation: That ASHP collaborate with other national pharmacy organizations to develop a lexicon defining terminology pertaining to collaborative practice in order to improve public recognition and facilitate provider status legislation.

Background: The terminology and regulations for pharmacist collaborative practice vary greatly across states. Consistency in terminology across state lines would improve visibility and recognition of pharmacists providing care among patients, providers, and legislators, furthering ASHP's goal to pass provider status legislation. Acknowledging the array of existing levels of practice allowed by state laws, a lexicon should be developed and promoted.

16. Education for Rare (Orphan) Diseases

Melinda (Mindy) Burnworth (AZ), Carol Rollins (AZ)

Recommendation: To strongly advocate that ASHP revise policy 1413, Ensuring Effectiveness, Safety, and Access to Orphan Drug Products, to be more inclusive of educating pharmacists and other healthcare providers about rare (orphan) diseases.

Background: Rare diseases are defined as those affecting less than 200,000 individuals. Unfortunately, many practitioners do not receive formal training or education on rare (orphan) diseases in didactics, forcing on-the-job education. Because of limited awareness of rare (orphan) diseases many patients may go undiagnosed and untreated for many years. Revision of policy 1413 will group rare disease and orphan drug education together, thus, promoting education and awareness of both rare (orphan) diseases and orphan drugs simultaneously. Dare to Care for Rare.

17. Dosing Considerations in Extracorporeal Treatment Modalities

Casey White (SCSS)

Recommendation: Request that ASHP develop a consensus statement or other appropriate document for guidance on dosing considerations for extracorporeal treatment modalities.

Background: None

18. Pharmacists Leadership in Compliance and Education for Pharmacist Clinical Services Billing and Reimbursement

Melanie A. Dodd (NM), Juliann Horne (NM)

Recommendation: To encourage pharmacists to serve as leaders in the development and implementation of strategies to optimize compliance for billing and reimbursement for pharmacist clinical services.

Background: Historically, pharmacists have not been engaged in direct billing or able to bill for their clinical services. In addition, billing compliance for pharmacist clinical services is very complex and often misunderstood, in our very diverse healthcare environment. Therefore, we would advocate for appropriately trained pharmacists to serve as leaders and educators of compliance officers, billing/coding staff, and other essential operational team members in this area.

19. Medical Aid in Dying, Hospice, and Palliative Care Education

Melanie A. Dodd (NM), Juliann Horne (NM)

Recommendation: It is recommended that ASHP advocate for and provide education to pharmacists, other healthcare providers, and our communities on the role of hospice and palliative care in healthcare, including education on palliative care concepts such as medical aid in dying, palliative sedation, and assisted suicide.

Background: Frequently, healthcare providers, patients, and their caregivers have insufficient awareness and understanding of the various care options at the end of life, resulting in missed opportunities for hospice and palliative care referrals. Pharmacists can play a key role in educating the patient, families, and their healthcare team. Specifically, appropriately trained pharmacists can participate in family meetings when counseling patients around difficult conversations, such as decisions for medical aid in dying, palliative sedation, or assisted suicide.

20. ASHP's Advocacy and PAC Advisory Committee

Melinda Burnworth (AZ), Carol Rollins (AZ), Leigh Briscoe-Dwyer (NY), John Hertig (IN), Maria Serpa (CA) Kathy Donnelly (OH), Jeff Little (MD), Erin Fox (UT), Katelyn Dervay (FL), Julie Groppi (VA)

Recommendation: To encourage ASHP to create a position statement on advocacy as a key part of pharmacy's professional responsibility.

Background: Successful advocacy can open new doors for pharmacists to use their extensive clinical knowledge to care for their patients and lead the profession forward. Unfortunately, many practitioners do not receive formal training or education on how to advocate, from identifying their elected officials to advancing a new bill (such as pharmacists as providers) nor the importance of advocacy. A position statement that emphasizes advocacy as part of professional responsibility will highlight the value of advocacy for the pharmacy profession and our patients. A search of ASHP policy, positions, and guidelines did not identify a document dedicated solely to advocacy. Advocate because your patients need you.

21. Pharmacist Prescribing of Controlled Substances

Julie Groppi (VA), Heather Ourth (VA Alternate Delegate), Kristy Butler (OR), SACP, Veterans Affairs

Recommendation: ASHP to advocate for the ability of pharmacists to prescribe controlled substances, to include promoting specific language outlining this ability within state practice acts.

Background: With an increased need for pharmacist involvement in mental health, pain management and substance use disorders, pharmacists practicing as advanced practice providers should have the ability to prescribe controlled substances. Currently the DEA only allows pharmacists licensed in states with explicit language outlined in the state practice acts to obtain and hold a DEA registration. Currently only 7 states that have outlined this ability for pharmacists. With patient care gaps and the current opioid epidemic, it is essential that pharmacists that possess competency and skills to provide these services should have the full capacity to prescribe autonomously for their patients to improve access to care.

22. Summer Meeting in Indianapolis

John Hertig (IN), Tate Trujillo (IN), Amy Heck (MI)

Recommendation: ASHP should seriously examine Indianapolis as a site for a future ASHP summer meeting.

Background: As a host for Super Bowl 46, final fours, and countless NCAA championships, Indianapolis should receive thoughtful consideration as a host for an ASHP meeting.

23. Banning Advertisements for 1-800-Bad-Drug

Diane Fox (TX), Tammy Cohen (TX), Sidney Phillips (TX), Jeff Wagner (TX), Shane Green (TX), Ryan Roux (TX), Michael Dickens (ID), Carol Rollins (AZ)

Recommendation: ASHP should work with regulators to ban direct to consumer advertising of 1-800-Bad-Drug promotions to recruit patients for legal proceedings concerning adverse drug reactions.

Background: Advertising media (airport posters, TV, radio and magazines) is used to recruit clients who have experienced adverse drug reactions with the aim to engage legal proceedings. Many times the adverse reaction is a known issue with the medication. This increases the cost of healthcare for everyone.

24. Antimicrobial Stewardship Program Support

Casey White (SCSS)

Recommendation: Request ASHP consider developing policy to advocate for dedicated workforce to meet the needs of antimicrobial stewardship programs, including adequate support of pharmacist time, resources, and other needs, including implementation of antimicrobial stewardship programs.

Background: None

25. ASHP Opposes Federal Budgetary Proposals that Impede the Practice of Pharmacy

Brian Kawahara (CA)

Recommendation: The ASHP Board of Directors create a policy opposing federal budget proposal that impede or negatively affect the advanced practice of pharmacy research post-graduate training like fellowships and residencies.

Background: The proposed 2018 federal budget would severely slash spending to federal healthcare programs that support program that can improve the practice of pharmacy research related to patient care. The loss of funding for research or training programs will negatively impact the practice of pharmacy and the profession's ability to optimize patient care and move the practice of pharmacy and health delivery forward.

26. Encourage State Affiliate and ASHP Collaboration on Shared Sales of Limited Publications

Lindsay Massey (KS, UT)

Recommendation: To recommend that ASHP collaborate with state affiliates for share sales of specific ASHP publications for the purpose of stimulating local affiliate membership and financial growth.

Background: I noticed recently that the local state APhA affiliate was selling limited APhA publications through the state affiliate website. If limited publications, such as the new USP 800 book that was released, were driven and sold through local affiliates, this could: 1) drive more potential members to the local affiliates; website to provide a vehicle to better connect and communicate affiliate activities; 2) possibly increase membership on the local level; and 3) possibly provide a way for ASHP to financially support states (shared revenue on sales).

27. Simultaneous Leadership in ASHP and State Affiliates

Micah Cost (TN, IA, WI, KS, CO, TX, IN, CT, AL, MI, OR, IL, OH, MA, KY, MS, PA, SCSS, SPPM, SACP, SICP, SOPIT)

Recommendation: ASHP should explore ways to support its members who serve in elected nonfiduciary roles to simultaneously serve in elected ASHP and state affiliate leadership positions in an effort to foster collaboration and congruence with state affiliates and member engagement.

Background: None

28. Generic Lifesaving Medication Production in the U.S.

Sidney Phillips (TX), Steve Grey (CA) and others (LA, AL, SC)

Recommendation: ASHP to take action to encourage governance entities to develop programs that financially support the U.S. production of generic lifesaving medications by multiple manufacturers.

Background: Currently many longstanding generic medications that are needed to save patients' lives in health systems are produced by one or two manufacturers. Examples of these medications are sodium bicarb, epinephrine, dopamine, neostigimine, and many others. Many of these manufacturing plants are not located in the continental United States. Manufacturing shortages or product outages by the manufacturer results in direct impact to patient care and increased cost to the overall health system through the purchase of these drugs during times of shortages from gray market distributors or compounding pharmacies. The federal government has long supported manufacturers in many industries to ensure that production of food and other goods occurs in the United States and with a wide variety of producers to prevent shortages. It is time that government resources are dedicated to ensure that the production of lifesaving generic drugs is not jeopardized by single or few producers based in foreign countries.

29. Announcement (and Presence) of Slate of Candidates for President, BOD, Section Chairs and Directors-at-Large During the House Proceedings

Melinda (Mindy) Burnworth, Carol Rollins (AZ, CO, MO)

Recommendation: To encourage ASHP to evaluate a consistent method of announcing and showcasing the slate of candidates for various positions that allows for highest visibility and timeliness.

Background: Recognition of the slate of candidates for President, BOD, and Section Chairs and Directors-at-Large during the House Proceedings is an important component. To maintain a consistent approach, consider seating all candidates in the same spot in the room and when each candidate's name is read aloud, project each candidate's picture on the overhead screen (similar to the Fellow Recognition Program). This will require the same amount of time as past proceedings but will eliminate the audience from searching around the room for the individuals nominated and may also gently encourage attendance by the candidates.

30. Providing Opportunities for Pharmacists Working in Health Plans and PBMs

Shane Green (TX)

Recommendation: ASHP evaluate the opportunities to connect and provide resources for pharmacists actively engaged in monitoring or overseeing payer and/or PBM contracts such as pharmacists working in health-system owned health plans and PBMs.

Background: There is a growing need for pharmacists who work within health-system health plans, Medicare advantage/part D plans, to connect and share common concerns and best practices. While AMCP is available to those pharmacists, the environment within that organization is more exclusively networking for business decisions/contracting (e.g., between pharmaceutical company and PBMs or large insurance companies and manufacturer rebates). What is lost is the consideration of the patient and the “clinical touch.” I feel ASHP can close the gap for pharmacists in this arena who are still fiscally responsible, but who also still consider the impact of their decision on members they serve and the physician networks they are responsible to.

31. Expansion of PGY2 Pain Residency Programs

Julie Groppi (VA fraternal delegate), Heather Ourth (VA alternate delegate), fraternal delegates from USPHS, Navy, Air Force, MO

Recommendation: ASHP to evaluate the need to change requirements for PGY2 Pain and Palliative Care residency program standards to allow increased flexibility for supporting chronic pain management roles.

Background: With an increased need for pharmacist involvement in pain management and substance use disorders, there is a need to expand current PGY2 residency options for pain. Many facilities struggle with meeting programmatic standards for palliative care and therefore are unable to meet current requirements for an ASHP accredited PGY2 program in pain. Flexibility should be allowed for programs to determine appropriate rotations for their organization such as SUD and chronic pain while preserving core competencies of the current program.

32. Publicly Available Quality Metrics for Manufacturers

Erin Fox (UT)

Recommendation: ASHP should advocate for the availability of publicly available quality metrics from manufacturers to ensure health systems can purchase medications based on quality.

Background: None

33. Interprofessional Competencies

Paul Walker (MI)

Recommendation: That ASHP encores the competencies of the interprofessional education collaborative and integrate these competencies into its residency competencies and practice policies.

Background: Residents and pharmacists must demonstrate/develop interprofessional competencies in order to participate effectively in interprofessional teams and provide team-based care. These standardized competencies are widely accepted as those pharmacists and other health professionals should demonstrate.

34. Medicines of Animal Origin

Casey White (SCSS)

Recommendation: Review the cultural and clinical considerations for medicines of animal origin.

Background: Often the needs and desires of patients with cultural issues surrounding medicines of animal origin are not addressed, and when they are, the evidence/guidelines are often lacking for clinician guidance.

35. ASHP Support Use of Personal, Name, NPI, and DEA Numbers by CDTM and Prescribing Pharmacists Instead of the Referring MDs Name and Numbers

Steven Gray (CA)

Recommendation: ASHP supports requiring all pharmacists to use their own names, NPI and DEA numbers when prescribing, ordering, initiations, or furnishing 'Rx only' item and tests.

Background: Many pharmacists are not doing so because of confusing law and expectations. This puts them at risk and the MDs and does not show personal, professional assumptions of responsibility.

36. ASHP House of Delegates Training Materials

Carol Rollins (AZ), Mindy Burnworth (AZ), Michael Dickens (ID)

Recommendation: Recommend that ASHP develop electronic-based training materials to assist state affiliate chapters recruit potential delegates to the House of Delegates (HOD) and train those elected.

Background: Recruiting delegates is a difficult process, especially for states with limited ASHP membership and/or members spread over a wide geographic area. One contributor to difficulty in recruiting is giving potential candidates an accurate view of what occurs in the HOD and the responsibilities involved with being a delegate. Electronic-based training materials that provide actual (or "mock") HOD activities would allow interested members to better understand procedures and increase their comfort level to be an active HOD participant.

37. Guidelines for Care of Transgender Patients

OR (no name supplied; contact Sarah Deines, Zach McCall, and Daniel Rackham)

Recommendation: ASHP should develop guidelines for care of transgender patients to further and more widely support the Council on Therapeutics policy regarding therapeutic and psychosocial considerations of transgender patients.

Background: Supported by Section of Clinical Specialists and Scientists.

38. PBM Transparency around DIR Fees

Nishaminy Kasbekar (PA)

Recommendation: ASHP advocate and create a policy statement for PBM transparency around direct and indirect remuneration fees.

Background: None

39. Drug Take-back and Appropriate Disposal

Kristy Butler (SACP and OR)

Recommendation: Recommend that ASHP creates or revises existing policy or guideline(s) to provide greater support and guidance for drug take-back and appropriate disposal.

Background: Although briefly discussed in Policy 1603, we feel a more robust policy or guideline is needed to address the importance of and best practices for drug tack-back and appropriate disposal. This would complement policies for Controlled Substance Diversion Prevention, Stewardship of Drugs with Potential for Abuse, and Drug Theft.

40. Pharmacists' Roles in Mental Health and Illness

Ashley Schaber (USPHS), Julie Groppi (VA), Renee Robinson (USPHS), Heather Ourth (VA), Alice Moss (Navy), Winnie Lok-Park (Air Force), Lara Nichols (AK), Amy Sipes (MO), (COT), Gwendolyn Thompson (Army)

Recommendation: Recommend that ASHP review pharmacists' roles in mental health (MH) and associated conditions.

Background: There is evidence that positive mental health is associated with improved health outcomes. According to the CDC, "only about 17% of U.S. adults are considered to be in a state of optimal mental health" (www.cdc.gov/mentalhealth/basics.htm). Roles for MH pharmacists are expanding due to shortages and increased need for patient access to care. ASHP should evaluate the pharmacist roles in screening and management of substance use and mental health disorders; encourage MH education for pharmacists; and advocate for advance practice roles for pharmacists as mental health team leaders.

41. State Level Provider Status Toolkit

Adam Porath (NV)

Recommendation: Recommend ASHP develop a state level provider status toolkit.

Background: There are few consolidated resources for state level provider status advocacy efforts.

42. Summer Meetings in Florida

Gary Dulin (FL)

Recommendation: If LeBron James can bring his talents to South Beach, we would recommend that ASHP look at Miami Beach for a summer meeting. There is life outside of Orlando.

Background: None

ASHP Board of Directors, 2017–2018

Appendix X

Am J Health-Syst Pharm. 2017; 74:e429



PAUL W. BUSH
PRESIDENT AND CHAIR
OF THE BOARD



LISA M. GERSEMA
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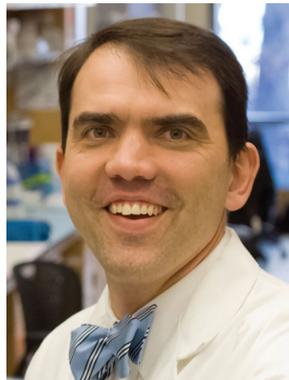
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Caring for patients and frontline pharmacy staff

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Paul W. Bush, Pharm.D., M.B.A., BCPS, FASHP, Duke University Hospital, Durham, NC.

Address correspondence to Dr. Bush (prez@ashp.org).

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As leaders in health-system pharmacy, we should support our staff by serving as their advocates.



It is a privilege to have the opportunity to serve you, ASHP, and the profession. Please indulge me for a moment as I recognize a few special people who have provided invaluable support throughout the years. Thank you to my fellow Board members—past and present—and the ASHP staff. I'd also like to thank the numerous individuals with whom I have worked across the country, especially in the 3 states I have practiced—Michigan, South Carolina, and North Carolina.

Thank you to my practice colleagues at Riverside Osteopathic Hospital, Detroit Osteopathic Hospital, St. John Hospital and Medical Center, the Medical University of South Carolina Medical Center, and my current team at Duke University Hospital. Thank you to my faculty colleagues at Wayne State University, the Medical University of South Carolina, University of North Carolina Eshelman School of Pharmacy, and Campbell University College of Pharmacy and Health Sciences.

As many of you know, I have a passion for training technicians, students, and residents. I'd like to thank all of

my learners and trainees, past and present. You are special colleagues of whom I am so proud—working with you has been a gift for which I am eternally grateful.

My thanks also to the many dedicated colleagues I have worked with through ASHP and Vizient UHC and to all of the administrators, pharmacists, residents, students, and technicians with whom I have collaborated, been inspired by, and learned from over the years. I would like to specially thank my good friend Toby Clark, who is with us in spirit today. For those of you who did not know him, Toby was a tremendous mentor and friend to me and I know for many of you as well. We both lived in Charleston, South Carolina. We had wonderful discussions about family and our profession, most often over good food and wine as we enjoyed the view of Charleston Harbor.

Finally, I would like to thank family—my wonderful wife Julie, son Justin, daughter Sarah, and son-in-law John for supporting me as I pursue my career. Our grandchildren, Mara and Beau, who are here today, have added a whole new inspiring dimension to our lives. My brothers Chris, Fritz, and Mark, who have joined me in carrying on the Bush family spirit. How awesome you all are.

I must admit that I felt humbled and somewhat overwhelmed when I

received the call informing me that I had been elected to be your president. My predecessors are all outstanding individuals whom I admire, respect, and consider instrumental leaders in our profession.

ASHP members as leaders of our profession

Everyone in this room today is a leader. Maybe you see yourself as a leader and maybe you don't, but simply by coming to the Summer Meetings, you are leaders. Leaders influence thoughts, attitudes, and behaviors. Leaders set direction, see what lies ahead, visualize what can be achieved, encourage, and inspire. Strong leadership is important because leaders attract talented staff and enable them to work effectively to fulfill an organization's goals. It is important because it is the best way to get the best people to do their best work. In today's knowledge-based environment, a leader is not successful by commanding people to work harder, smarter, or faster. Effective leaders inspire people's capacity to adapt, innovate, and reinvent their organization by examining what has worked, what needs to be changed, and what needs to be abandoned.

Senior pharmacy leaders are critical to an organization's success. They must own and champion the vision,

mission, and plan by being visible, public, and active communicators. They must invest their personal time and attention in following through on actions. They must be known as advocates for change and progress as they take personal initiative and challenge the status quo to propel the organization toward the vision. Effective leadership is critical at all levels, including pharmacy residents, front-line pharmacists, clinicians, coordinators, managers, and senior pharmacy leaders.

High-performing pharmacy programs develop when strong leadership is found throughout the organization. Although it is essential that chief pharmacy officers are able to successfully guide staff as well as get support from senior leadership, it is also important for strong pharmacy leadership to be present within many other settings and at all levels of the organization.

It is very important for practitioners to lead as well—examples include pharmacy clinicians with their patient care teams, pharmacists on interdisciplinary information technology teams, medication safety pharmacists with their patient safety or nursing peers, and supervisors in pharmacy distribution areas.

Contemporary pharmacy leaders have made outstanding progress in adopting practice models that allow staff to move closer to patients in both the inpatient and ambulatory care settings. By implementing new patient care roles, pharmacists have made significant and measurable improvements in the quality and safety of medication use. Through their direct involvement, pharmacists and technicians have greatly improved the continuity of care for patients as they transition from one setting to the next.

Supporting the pharmacy workforce

I wanted to start this morning by talking about leadership, because I think it is crucial to achieving my primary objective as president, which is to advance both our thinking and

our actions relative to our workforce. When it comes to our workforce, ASHP and pharmacy leaders like you can support our pharmacists, technicians, and trainees who are on the front-line 24-7 caring for our patients, both formally and informally, on 3 fronts: building staff resilience, providing technician training and support, and encouraging clinicians to be leaders.

Promoting a resilient work environment and a healthy work-life balance. I have had the opportunity to work with hundreds of pharmacists and technicians in diverse settings in several health systems throughout my career. This experience has provided me with a tremendous opportunity to understand how our workforce provides exceptional care for our patients while managing production pressures and navigating the often-stressful business of pharmacy.

Pharmacy leaders are extremely busy. We are often consumed with the many challenges of dealing with external pressures brought on by the competitive healthcare environment. This can create a blind spot to equally important internal organizational threats such as workforce stress and burnout. We all know what stress feels like, and most of us encounter it to some degree every day. Our frontline staff routinely respond to urgent requests for drug therapy recommendations or have challenging discussions with patients or their families while also overseeing the medication-use process for their multidisciplinary teams, patient care units, or clinics. They become skilled multitaskers and do it all day long. This prolonged stress is a precursor to a more serious syndrome commonly referred to as burnout. Burnout is characterized as a state of physical, emotional, or mental exhaustion combined with doubts about personal competence and the value of one's work.

Burnout and stress aren't all in your head; they're common among healthcare workers. Factors that could lead to burnout in the work environment include time pressure, lack of

control over work processes, role conflict, and relationship challenges among groups. These characteristics, combined with personal predisposing factors and the emotional intensity of clinical work, put our staff at high risk for burnout.

This concerns me. The literature increasingly shows that as many as 50% of the healthcare workforce experiences some level of burnout that can be associated with negative outcomes such as substandard work and mistakes. A research team that I worked with at Duke recently assessed the prevalence of burnout in health-system pharmacists. The researchers used a technique known as the Maslach Burnout Inventory. For those of you who aren't familiar with it, the Maslach Burnout Inventory is a survey tool that is used to quantify burnout in healthcare settings. After conducting the survey, the Duke team found that 1 in 5 health-system pharmacists was at risk for burnout. There is also evidence that pharmacy residents have high levels of perceived stress, and this is highly correlated with these same negative outcomes.

The good news is that there are ways to stay resilient and restore our ability to bounce back and respond to stress in a healthy way. Data show that healthcare workers who are resilient do a better job of caring for patients and are less likely to make errors or leave practice. Obviously, it is in our profession's best interest to cultivate a resilient work environment. Doing so will improve the quality of care and the sustainability of our frontline workforce.

To promote resiliency and a healthy work-life balance, we should try to better understand our work environment and acknowledge and assess the potential for burnout in our workplace. We can harness the power of leadership as a solution by developing and implementing targeted strategies such as aligning values, strengthening culture, and providing peer support. We should promote flexibility and work-life balance and provide

resources to promote resilience and self-care.

This topic of preventing staff burnout is of tremendous interest to me. In fact, ASHP is cosponsoring an important new initiative on resilience. It is called the Action Collaborative on Clinician Well-Being and Resilience and is coordinated by the National Academy of Medicine. We are the only pharmacy organization that is involved with this initiative. Together, we—physicians, nurses, and pharmacists—are building a collaborative platform for supporting and improving clinician well-being and resilience across multiple organizations, including clinician and consumer groups as well as healthcare organizations and policymaking bodies.

I'm really excited about this initiative! It paves the way for a series of meetings and workshops—grounded in evidence-based knowledge—first to assess and understand the underlying causes of clinician burnout and then to advance solutions to reverse the trends in clinician stress and burnout. We'll be sure to keep all of you, the ASHP members, informed about any discoveries and recommendations we make.

Supporting pharmacy technicians. Now I would like to explore with you ways we can support the training and development of our technician workforce. We need to help make pharmacy a career—let me repeat that, a career—for technicians and develop their leadership capability.

The role of pharmacy technicians has dramatically expanded in recent years. Technicians continue to be highly involved with traditional supply chain and medication preparation activities while increasingly adopting roles in transitions of care, medication assistance, quality assurance, information systems management, and supervision.

The job outlook is bright! Technician employment is projected to increase 10% between now and 2022. This means we need to recruit, educate, and train many more technicians

than we do today. Our profession must act urgently to increase technician education and training programs to meet current and future demands. We must increase support for our technicians. If we don't, we will not be able to provide the care that our patients deserve. Supporting our technicians is good for patients and for our frontline pharmacists. Well-trained technicians provide the support our pharmacists need to allow them time to work more closely with their patients.

Think about this for a minute: What would happen if we were to commit to educating, training, and developing pharmacy technicians at the same intensity that we commit to students, residents, and pharmacists? Just think about that.

I am extremely passionate about this, and I have been for years. At each of the 4 health systems where I have worked, I have developed education and training programs that include pharmacy technician development. The first program was more than 30 years ago, when the Michigan Pharmacist Association developed the first pharmacy technician certification exam. I developed a course that my colleagues and I taught 1 night per week for 10 weeks to help technicians in southeastern Michigan prepare for the exam. We did this twice a year for many years. Not only was this very rewarding for me personally, but years after completing the program technicians have thanked me for helping them prepare and successfully pass the exam. While serving as the director of pharmacy in inner-city Detroit, I led a technician-based medication administration program in response to a severe shortage of registered nurses. When I arrived in Charleston, the same educational need existed, so I offered the course again.

At the Pharmacy Technician Stakeholders Conference in February, we learned there should be multiple competency levels—such as the technician in training, the entry-level generalist, and the advanced technician specialist or coordinator. Most technicians

in health systems will work their way up to the advanced levels. There could be a unique compensation program for each level commensurate with the value the position provides. This will improve technician engagement as well as the quality and consistency of services provided. It will also establish a more stable and experienced workforce.

To provide technicians with more career opportunities, we need to redesign and expand our approach to education and training. Today there are approximately 275 accredited training programs; about the same number are unaccredited. These programs are primarily at community colleges and technical schools, and they have varying enrollments. To meet our workforce requirements, health systems need to work closely with these programs through more extensive partnerships. We should develop innovative approaches for student recruitment, education, and training—with much more of them occurring at our health-system facilities. As an example, we at Duke have partnered with Durham Technical Community College to offer classes on our hospital campus that are taught by members of our staff. This is rewarding for our staff, and it has resulted in enhanced learning for the students. I encourage you to consider this approach and to support existing programs much more extensively.

We also should develop and operate many more health-system accredited programs, by which I mean “employer-based” programs. Let me tell you why this is possible today. There's now an accredited distance-education program that we can use for the didactic content in conjunction with presentations and discussion sessions provided by preceptors in the hospital. A distance-education format will allow a health system to have a centrally coordinated program with hospital-based students, where the students receive experiential education and training. For example, a program director based at a multihos-

pital health system's flagship or home office could direct a program offered at several hospitals in the system. Course content from the accredited distance-education provider could be offered to technicians in training in the morning, and in the afternoon the students could be deployed to the pharmacy facilities for precepted experiential training. This format can bring the availability and affordability of accredited pharmacy technician education to hospitals large and small across the country.

This past year at Duke University Hospital, we launched the Pharmacy Technician Professional Development Committee. I am the administrative liaison, and the committee is chaired by 1 of our senior pharmacy technicians, Malphus Stroud. Malphus is a clinical research specialist at Duke's Investigational Drug Service and the recipient of the 2016 Founders Award for Outstanding Service and Dedication from the American Association of Pharmacy Technicians. He is a shining example of what well-trained career technicians can accomplish when we champion their professional development.

To support our currently employed pharmacy technicians, we need to dramatically increase health-system-based technician professional development programs. For instance, we offer 2 30-minute Accreditation Council for Pharmacy Education–approved continuing-education sessions every month. They're available to technicians across the Duke University Health System. The format is a 20- to 25-minute presentation, followed by a panel discussion or question-and-answer session. Presenters include technicians, pharmacists, and individuals from other disciplines.

At Duke, we also use ASHP's online continuing-education programming. As with pharmacists' continuing professional development, the topics are planned and sequenced in a manner that will support an informed work-

force as well as career development. I believe this type of program is instrumental to our technicians' career development and to the success of health-system-based pharmacy education and training programs.

So I ask you again: What would happen if health-system pharmacy leaders and their pharmacists were to commit to educating, training, and developing pharmacy technicians at the same intensity that we commit to students, residents, and pharmacists? The answer is that we would have a tremendous pharmacy technician workforce, which would allow our pharmacists to work more closely with patients to improve care.

Developing clinician leaders.

I'd like to finish up with a contemporary view on the leadership element—specifically a call to action to develop pharmacy leaders who maintain a clinical practice. We all know what a pharmacist's white coat means—it's a symbol of clinical service and dedication to providing outstanding patient care. While our pharmacy leaders often wear many hats, I can envision a future where there are more pharmacy leaders who wear many coats—a future where pharmacy executives are administrative leaders with active clinical practices.

I believe we should offer opportunities for our clinicians to be leaders of our pharmacy divisions and departments, and residents trained in pharmacy administration should develop and maintain an active clinical practice. The majority of pharmacy leaders today are in traditional administrative positions focused on leadership and management. More and more often, pharmacy leaders have become healthcare executives at the vice president level, leading pharmacy services in academic medical centers and health systems. I've noticed an increasing number of pharmacy leaders who continue to devote a portion of their time to clinical practice. This is most easily accommodated when

the leader maintains a part-time ambulatory care practice, but others have been successful in clinical consulting roles. This mirrors our physician colleagues who have ascended to senior leadership roles as chief executive officers, chief operating officers, and medical directors.

In my experience, the majority of physician leaders maintain a clinical practice and stay connected with their patients. Many nurse clinicians who have assumed clinical leadership roles continue their clinical practice as well. Given the significant need for more leaders in our profession, I believe we should embrace this trend for our clinician pharmacists. We need to encourage our well-trained clinicians to continue to work on their leadership skills so that as they proceed in their careers, they will successfully assume formal leadership roles.

Conclusion

As leaders in health-system pharmacy, we should support our staff by serving as their advocates. Let's implement new strategies to develop our staff's resilience, develop support programs for our technicians, and develop leaders including clinician leaders.

Ladies and gentlemen, I believe that genuine pharmacy leaders routinely invest time to provide the opportunity for students, residents, technicians, staff, and professional colleagues to learn from you. No matter what your current position—even if you're the chief pharmacy officer—I encourage you to personally develop and offer learning experiences to those around you. All of us, and especially our patients, will be better for it.

Disclosures

The author has declared no potential conflicts of interest.

Additional information

Presented at the ASHP Summer Meetings, Minneapolis, MN, June 6, 2017.

House of Delegates

REPORT ON IMPLEMENTATION OF 2016

ASHP HOUSE OF DELEGATES ACTIONS AND RECOMMENDATIONS

Council on Therapeutics 1601: Safety of Intranasal Route as an Alternative Route of Administration

To encourage the development of institutional guidance and advocate for further research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To foster the development of educational resources on the safety of intranasal administration of drugs not approved for that route.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Pharmacy Management 1602: Drug Product Supply Chain Integrity

To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate for improved transparency so that drug product labeling include a readily available means to retrieve the name and location of the facility that manufactured the specific lot of the product; further,
To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product and its raw materials; further,

To foster increased pharmacist and public awareness of drug product supply chain integrity; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

This policy supersedes ASHP policy 1503.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Therapeutics 1603: Stewardship of Drugs with Potential for Abuse

To advocate for the inclusion of a clinically appropriate indication of use, the intended duration, and the goals of therapy when prescribing drugs with potential for abuse; further,

To encourage pharmacists to engage in interprofessional efforts to promote the appropriate, but judicious, use of drugs with the potential for abuse, including education, monitoring, assessment of clinical progress, and discontinuation of therapy or dose reduction, where appropriate; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of drugs with potential for abuse, including engaging in strategies to detect and address patterns of use in patient populations at increased risk for adverse outcomes; further,

To facilitate the development of best practices for prescription drug monitoring programs and drug take-back disposal programs for drugs with potential for abuse.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Therapeutics 1604: Appropriate Use of Antipsychotic Drug Therapies

To advocate for the documentation of appropriate indication and goals of therapy to promote the judicious use of antipsychotic drugs and reduce the potential for harm; further,

To support the participation of pharmacists in the management of antipsychotic drug use, which is an interprofessional, collaborative process for selecting appropriate drug therapies, educating patients or their caregivers, monitoring patients, continually assessing outcomes of therapy, and identifying opportunities for discontinuation or dose adjustment; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of antipsychotic drugs, including engaging in strategies to detect and address patterns of use in patient populations at increased risk for adverse outcomes.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Therapeutics 1605: Safety of Epidural Steroid Injections

To encourage healthcare providers to 1) inform patients about the significant risks and potential lack of efficacy of epidural steroid injections, 2) request their informed consent, and 3) inform patients of alternative therapies and their risks and benefits; further,

To recommend pharmacist involvement in the medication-use process associated with epidural steroid injections when such injections are medically necessary.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Therapeutics 1606: Drug Dosing in Renal Replacement Therapy

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in renal replacement therapy; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in renal replacement therapy; further,

To collaborate with stakeholders in enhancing aggregation and publication of data on the pharmacokinetics and pharmacodynamics of drug dosing in renal replacement therapy.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Therapeutics 1607: Use of Methadone to Treat Pain

To acknowledge that methadone has a role in pain management and that its pharmacologic properties present unique risks to patients; further,

To oppose the payer-driven use of methadone as a preferred treatment option for pain; further,

To advocate that pain management experts, payers, and manufacturers collaborate to provide educational programs for healthcare professionals on treating pain with opioids, including the proper place in therapy for methadone; further,

To advocate that all facilities that dispense methadone, including addiction treatment programs, participate in state prescription drug monitoring programs.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Therapeutics 1608: Therapeutic Indication in Clinical Decision Support Systems

To advocate that healthcare organizations optimize use of clinical decision support systems by including the appropriate indication for medications.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Education and Workforce Development 1609: Pharmacy Technician Training and Certification

To advocate that Pharmacy Technician Certification Board (PTCB) certification be required for all pharmacy technicians; further,

To advocate that all pharmacy technicians maintain PTCB certification; further,

To support the position that by the year 2020, the completion of a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required to obtain PTCB certification for all new pharmacy technicians; further,

To foster expansion of ASHP-ACPE accredited pharmacy technician training programs.

This policy supersedes ASHP policy 1519.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. This policy may be reviewed again in 2017 based on outcomes of the 2017 Pharmacy Technician Stakeholder Consensus Conference.

Council on Education and Workforce Development 1610: Career Opportunities for Pharmacy Technicians

To promote pharmacy technicians as valuable contributors to healthcare delivery; further,

To develop and disseminate information about career opportunities that enhances the recruitment and retention of qualified pharmacy technicians; further,

To support pharmacy technician career advancement opportunities, commensurate with training and education; further,

To encourage compensation models for pharmacy technicians that provide a living wage.

This policy supersedes ASHP policy 0211.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to maintain robust [resources about pharmacy technicians](#), including promoting [advanced pharmacy technician roles case studies](#).

Council on Education and Workforce Development 1611: Developing Leadership Competencies

To work with healthcare organization leadership to foster opportunities, allocate time, and provide resources for pharmacy practitioners to move into leadership roles; further,

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

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

To encourage colleges of pharmacy and ASHP state affiliates to collaborate in fostering student leadership skills through development of co-curricular leadership opportunities, leadership conferences, and other leadership promotion programs; further,

To reaffirm that residency programs should develop leadership skills through mentoring, training, and leadership opportunities; further,

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

This policy supersedes ASHP policy 1518.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP and the ASHP Foundation provide many opportunities to foster leadership opportunities and skill development including the following: online resources, Pharmacy Leadership Academy, educational sessions at ASHP national meetings such as the ASHP Conference for Pharmacy Leaders and Midyear Clinical Meeting, Women in Pharmacy Leadership activities, and webinars.

Council on Education and Workforce Development 1612: Interprofessional Education and Training

To support interprofessional education as a component of didactic and experiential education in Doctor of Pharmacy degree programs; further,

To support interprofessional education, mentorship, and professional development for student pharmacists, residents, and pharmacists; further,

To encourage and support pharmacists' collaboration with other health professionals and healthcare executives in the development of interprofessional, team-based, patient-centered care models; further,

To foster documentation and dissemination of outcomes achieved as a result of interprofessional education of healthcare professionals.

This policy supersedes ASHP policy 1014.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to provide educational activities on the topic of interprofessional education.

Council on Education and Workforce Development 1613: Cultural Competency

To foster the ongoing development of cultural competency within the pharmacy workforce; further,

To educate healthcare providers on the importance of providing culturally congruent care to achieve quality care and patient engagement.

This policy supersedes ASHP policy 1414.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Pharmacy Management 1614: Controlled Substance Diversion and Patient Access

To enhance awareness by pharmacy personnel, healthcare providers, and the public of drug diversion and abuse of controlled substances; further,

To advocate that the pharmacy profession lead collaborative efforts to reduce the incidence of controlled substance abuse; further,

To advocate that pharmacists lead collaborative efforts by organizations of healthcare professionals, patient advocacy organizations, and regulatory authorities to develop and promote best practices for preventing drug diversion and appropriately using controlled substances to optimize and ensure patient access and therapeutic outcomes; further,

To advocate that the Drug Enforcement Administration and other regulatory authorities interpret and enforce laws, rules, and regulations to support patient access to appropriate therapies, minimize burdens on pharmacy practice, and provide reasonable safeguards against fraud, misuse, abuse, and diversion of controlled substances; further,

To advocate establishment of programs to support patients and personnel with substance abuse and dependency issues.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. The following initiatives have also been developed.

- Initiated a three-part webinar series on controlled substances diversion prevention and opioid prescribing.
- ASHP staff leadership provided at national meetings discussing opioid crisis and prevention of controlled substances diversion.
- ASHP advocacy supporting legislation to aid in addressing opioid crisis.

- Published the ASHP Guidelines on Preventing Diversion of Controlled Substances.
- Guidelines have been provided to more than 20 interprofessional organizations and government agencies.
- SM 2017 programming developed to support diversion prevention.
- Conference for Pharmacy Leaders 2016 conducted three-hour workshops on Preventing Diversion of Controlled Substances.

Council on Pharmacy Management 1615: Protecting Workers from Exposure to Hazardous Drugs

To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs; further,

To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of hazardous drugs; further,

To advocate that the Food and Drug Administration require standardized labeling and package design for hazardous drugs that would alert handlers to the potential presence of surface contamination; further,

To encourage healthcare organizations, wholesalers, and other trading partners in the drug supply chain to adhere to published standards and regulations, such as ASHP guidelines and United States Pharmacopeia Chapter 800, to protect workers from undue exposure to hazardous drugs.

This policy supersedes ASHP policy 0618.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Pharmacy Management 1616: Patient Experience

To encourage pharmacists to evaluate their practice settings for opportunities to improve the experience patients have with healthcare services and with the outcomes of their drug therapy; further,

To educate pharmacists and pharmacy personnel about the relationship between patient experience and outcomes; further,

To develop or adopt tools that will (1) provide a system for monitoring trends in the quality of pharmacy services to patients, (2) increase recognition of the value of pharmacy services, and (3) provide a basis for making improvements in the process and outcomes of pharmacy services in efforts to engage patients and improve their experience; further,

To facilitate a dialogue with and encourage education of patient experience database vendors to include the value of pharmacists and pharmacy services in the patient experience.

This policy supersedes ASHP policy 0104.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Pharmacy Practice 1617: Automated Preparation and Dispensing Technology for Sterile Preparations

To advocate that health systems adopt automation and information technology for preparing and dispensing compounded sterile preparations when such adoption is (1) planned, implemented, and managed with pharmacists' involvement; (2) implemented with adequate resources to promote successful

development and maintenance; and (3) supported by policies and procedures that ensure the safety, effectiveness, and efficiency of the medication-use process; further,

To educate patient safety advocacy groups and regulatory agencies on the capabilities and benefits of automation and technology for preparing and dispensing compounded sterile preparations, and to encourage them to establish expectation of adoption by health systems; further,

To foster further research, development, and publication of best practices regarding automation and information technology for preparing and dispensing sterile preparations.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Pharmacy Practice 1618: Integrated Approach for the Pharmacy Enterprise

To advocate that pharmacy department leaders promote an integrated approach for all pharmacy personnel involved in the medication-use process; further,

To advocate a high level of coordination of all components of the pharmacy enterprise across the continuum of care for the purpose of optimizing (1) medication-use safety, (2) quality, (3) outcomes, and (4) drug therapy.

This policy supersedes ASHP policy 0619.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Pharmacy Practice 1619: Preventing Exposure to Allergens

To advocate for pharmacy participation in the collection, assessment, and documentation of a complete list of allergens pertinent to medication therapy, including food, excipients, medications, devices, and supplies, for the purpose of clinical decision-making; further,

To advocate that vendors of medication-related databases incorporate and maintain information about medication-related allergens and cross-sensitivities; further,

To advocate that pharmacists actively review allergens pertinent to medication therapy and minimize patient and healthcare worker exposure to known allergens, as feasible; further,

To encourage education of pharmacy personnel on medication-related allergens.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Public Policy 1620: Promotion of Off-Label Uses

To advocate for authority for the Food and Drug Administration (FDA) to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers and their representatives; further,

To advocate that such off-label promotion and marketing be limited to the FDA-regulated dissemination of unbiased, truthful, and scientifically accurate information based on peer-reviewed literature not included in the New Drug Approval process.

This policy supersedes ASHP policy 1120.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP

advocacy, education, and communication efforts. ASHP continues to advocate that Congress and FDA ensure that communication of off-label uses of medications is truthful and scientifically accurate.

Council on Public Policy 1621: Timely Board of Pharmacy Licensing

To advocate that the National Association of Boards of Pharmacy (NABP) collaborate with boards of pharmacy to streamline the licensure process through standardization and improve the timeliness of application approval; further,

To advocate that NABP collaborate with boards of pharmacy and third-party vendors to streamline the licensure transfer or reciprocity process; further,

To advocate that boards of pharmacy grant licensed pharmacists in good standing temporary licensure, permitting them to engage in practice, while their application for licensure transfer or reciprocity is being processed.

This policy supersedes ASHP policy 0612.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to advocate with NABP on ways to increase speed and efficiency with respect to licensing. Further, ASHP has asked NABP to investigate the use of interstate compacts, similar to those used in nursing that may help expedite license application reviews.

Council on Public Policy 1622: Inclusion of Drug Product Shortages in State Price-gouging Laws

To urge state attorneys general to consider including shortages of lifesaving drug products within the definition of events that trigger application of state price-gouging laws.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to work with stakeholders such as the Campaign for Sustainable Rx Pricing on ways to prevent sudden price spikes of prescription drugs.

Council on Public Policy 1623: Home Intravenous Therapy

To support the continuation of a home intravenous therapy benefit under federal and private health insurance plans and expansion of the home infusion benefit under Medicare at an appropriate level of reimbursement for pharmacists' patient care services provided, medications, supplies, and equipment.

This policy supersedes ASHP policy 0414.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Council on Public Policy 1624: Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices

To advocate that Congress ban direct-to-consumer advertising for prescription drugs and medication-containing devices.

This policy supersedes ASHP policy 1119.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP, as a member of the Campaign for Sustainable Rx Pricing, continues to advocate for increased transparency with respect to manufacturers and their expenditures on advertising versus research and development.

Council on Therapeutics 1625: Tobacco, Tobacco Products, and Electronic Nicotine Delivery Systems

To discourage the use, distribution, and sale of tobacco, tobacco products, and electronic nicotine delivery

systems (e.g., vaporizers, vape pens, hookah pens, and electronic cigarettes and pipes) in and by pharmacies; further,

To advocate for tobacco-free environments in hospitals and health systems; further,

To seek, within the bounds of public law and policy, to eliminate the use and distribution of tobacco, tobacco products, and electronic nicotine delivery systems in meeting rooms and corridors at ASHP-sponsored events; further,

To promote the role of pharmacists in tobacco-cessation counseling and medication therapy management; further,

To join with other interested organizations in statements and expressions of opposition to the use of tobacco, tobacco products, and electronic nicotine delivery systems.

This policy supersedes ASHP policy 1224.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Section of Pharmacy Informatics and Technology 1626: ASHP Statement on Telepharmacy

To approve the ASHP Statement on Telepharmacy.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Opioid Infusion Monitoring (Recommendation): Dan Degnan (IN)

Recommend that ASHP work with the Association for the Advancement of Medical Instrumentation (AAMI) and the Promise to Amanda Foundation to develop policy regarding the continuous monitoring of patients receiving opioid infusions.

ASHP has participated in the National Coalition to Promote Continuous Monitoring of Patients on Opioids with AAMI for the last 1.5 years. We have partnered with AAMI to develop white papers and webinars. In addition, ASHP provided comments to TJC and AAMI on the prudent use of capnography and its usage for IV opioids.

Drug Removal by Extracorporeal Modalities (Recommendation): Kim Benner (AL)

To encourage research of drug removal by extracorporeal means to facilitate drug dosing.

ASHP's Council on Therapeutics will be discussing this and other extracorporeal therapies during its January 2017 meeting.

ASHP Sponsored 5K Run/Walk (Recommendation): Kim Benner (AL), Steve Riddle (WA)

To propose that ASHP host a 5K run/walk at a future Summer Meeting.

ASHP understands the importance of promoting healthy living at our meetings and in the daily lives of our members, patients and staff. ASHP will explore the potential viability of incorporating a 5K into our meetings keeping our meeting purpose and scheduling priorities in mind.

ASHP Position Statement on Assisted Suicide (Recommendation): Dan Degnan (IN)

That ASHP use the virtual House process and year-long Council review process to address the ASHP resolution that was referred at this meeting of the House of Delegates.

Since the House of Delegates voted to refer the recommendation in June, ASHP convened a Joint Council Task Force consisting of the Council on Pharmacy Practice, Council on Pharmacy Management, and the Council on Public Policy during ASHP Policy Week in September to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following

a presentation and question-and-answer session conducted by [Dr. Mark Hughes](#), the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors. The Board of Directors will consider the revised policy during its meeting in January, after which the House of Delegates and ASHP members will be able to debate the proposed revisions on ASHP Connect before the House considers the policy in June.

Projection of Policy Language During Chair-led Caucus (Recommendation): Carol Rollins (AZ)

That an electronic method be used to project Council wording of policies during caucus led by the Chair of the House (and amended language agreed upon through Connect).

ASHP will consider using projection at the first House caucus next year. While projection would make the discussion more clear, ASHP will need to consider several other factors in the decision.

Restricted Access to Medications Due to Pharmaceutical Company Initiatives Affecting Patient Care (Recommendation): Brian I. Kawahara (CA)

ASHP should develop a position regarding pharmaceutical companies restricting the purchase and distribution of agents based upon a social policy or initiative of the pharmaceutical company that may affect patient care.

Your recommendation will be shared with the ASHP Staff Policy Team as we prepare for the 2016 Council Week for consideration as an agenda item for the Council on Pharmacy Management. Your recommendation fits well into the overall discussions we have been having with the Council on the growing restrictions to medication access imposed by payers, manufacturers, and wholesalers.

ASHP does have policy addressing restricted drug distribution which is comprehensive, but it will be important to include the issues you have brought forward for additional considerations by the Council on Pharmacy Management.

Notification of Outcomes of Delegates Recommendations (Recommendation): Diane Fox (TX)

ASHP should continue to inform delegates and/or recommendation generators on the outcomes of their recommendations.

Delegates are contacted directly regarding their recommendation in the months following the House. In addition, the actions ASHP takes regarding recommendations are included in the Report on Implementation of Actions published on the House of Delegates website before the June meetings of the House.

Inclusion of Small Hospitals in ASHP Surveys (Recommendation): Diane Fox (TX)

ASHP should include rehabilitation hospitals, LTACs and small hospitals in their survey process to ensure all size hospitals can use the information obtained in surveys to improve services.

First, it should be noted that we do routinely include small medical/surgical hospitals in the ASHP National Survey each year and report the results in the Midyear presentation and the AJHP publication (sampling detailed below for 2015 survey). In fact, hospitals less than 100 beds made up 45% of the sample. We do not, however, include rehabilitation hospitals and LTAC hospitals in the national survey. An important aspect of the survey has been to be able to trend data over time and changing the methodology for sampling and hospital type would eliminate the ability to trend data. However, based on your recommendation, we are exploring how we might be able to survey rehabilitation and LTAC hospitals on practice issues (similar to the National Survey) and on issues unique to their setting. A key to the success of the ASHP National Survey has been having a single point of contact at each hospital (the Director of Pharmacy). We will explore the availability of a similar list for rehabilitation and LTAC hospitals. We would welcome any suggestions you have in this regard.

Nearly all other ASHP surveys are based on a sampling of members, and do not include or exclude specific hospital types.

Characteristic	Respondents		Nonrespondents		Surveyed		Population	
	n	%	n	%	n	%	n	%
All hospitals	325	22.7	1107	77.3	1432	29.3	4893	100
Staffed beds								
<50	68	22.9	229	77.1	297	17.1	1739	35.5
50-99	48	24.4	149	75.6	197	28.2	698	14.3
100-199	38	19.1	161	80.9	199	19.1	1041	21.3
200-299	44	22.0	156	78.0	200	32.2	622	12.7
300-399	44	22.0	156	78.0	200	55.9	358	7.3
400-599	49	24.5	151	75.5	200	67.6	296	6.0
≥600	34	24.5	105	75.5	139	100.0	139	2.8

Automated Preparation and Dispensing Technology for Nonsterile Preparations (Recommendation): Mike Storey, Karen Kier (OH)

ASHP advocate for best practices for the safe and efficacious use, preparation, and dispensing of nonsterile and compounded products including research of these best practices.

ASHP agrees this is a practice that needs more attention, recommended best practices, and furthered pharmaceutical training for pharmacy personnel compounding non-sterile preparations. The standardize 4 safety oral liquid expert panel is identifying practice areas of concern and a workgroup will develop in late 2017.

That ASHP Only Invite Current State Affiliate Members to Serve on Councils for ASHP(Recommendation): Natasha Nicol (SC, OR, SD, OH)

Recommendation: That ASHP only invite current state affiliate members to serve on councils for ASHP.

As part of the ongoing sunset review of existing ASHP policies, the Commission on Affiliate Relations voted in September 2015 to reaffirm policy 0118 which reads:

To give consideration to ASHP members who also hold membership in their state affiliate when making appointments to ASHP councils, committees, commissions, and other appointed bodies.

Whereas Commission members believed that it is in the best interest of the ASHP member to be involved at the affiliate level, it is important to note that it is not a requirement for ASHP members to be members of their respective state affiliate. [Please note that for antitrust purposes, ASHP cannot mandate membership in a member’s respective state affiliate as a requirement for active participation in ASHP.]

Appointments to ASHP’s councils, committees, commissions, and other appointed bodies are made by ASHP leaders according to their best judgment. State affiliate involvement is routinely considered in the appointment process. Traditionally, a high percentage of individuals serving on ASHP’s appointed bodies are leaders of their state affiliates. State affiliate membership is not the only criterion for appointment. The Commission will continue to review this policy on an ongoing basis every few years as it is an important aspect of ASHP policy.

Brown Bagging/White Bagging (Recommendation): Nishaminy Kasbekar (PA)

ASHP develop a policy to prohibit brown bagging/white bagging and endorse health systems insourcing of these products.

Your recommendation will be shared with the ASHP Staff Policy Team as we prepare for the 2016 Council Week for consideration as an agenda item for the Council on Pharmacy Management.

ASHP and the Councils have wrestled with this issue for many years, especially in light of the growing restrictions being put into place under ‘site of care’ initiatives and the growing use of limited drug distribution models. The Council on Pharmacy Management discussed limited distribution extensively this

past year and found ASHP policies to be comprehensive, though they will be making a recommendation to amend ASHP's policy on restricted drug distribution and the FDA's accountability on impact of REMS and drug access.

As part of this discussion, the Council did determine ASHP's policies on "any willing provider" were not strong enough and the Council will have this as an agenda item for 2016 Policy Week.

The Councils have also discussed the issue of patient own medications and have historically found that a complete ban on patient own medications would not be possible for all hospitals in all circumstances, but there have been a number of amendments to payer related ASHP policies to demonstrate our need to advocate against models that encourage brown bagging/white bagging and limited drug distribution models.

I have attached materials from the Council's 2016 deliberations for your review:

- 1) Issue Analysis from the Council on Pharmacy Management's background on Impact on Insurance Design on Patient Care Decisions
- 2) Related policies that supported Council discussions on Impact on Insurance Design on Patient Care Decisions

ASHP policies that are related to your recommendation include:

HEALTH-SYSTEM USE OF MEDICATIONS AND ADMINISTRATION DEVICES SUPPLIED DIRECTLY TO PATIENTS (0806)

Source: Council on Pharmacy Management

IMPACT OF INSURANCE COVERAGE DESIGN ON PATIENT CARE DECISIONS (1017)

Source: Council on Pharmacy Management

Updates on actions taken on your recommendation will be posted on the House of Delegates section of the ASHP website. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Evaluation of ASHP Staffing Model Service and Metrics for Health Systems (Recommendation): Sidney Phillips (TX)

ASHP develop and advanced staffing model/metrics and/or a comparative service for health systems that would provide interactive comparisons based on actual pharmacy services provided.

Your recommendation will be shared with the ASHP Staff Policy Team and including in ASHP staff meetings.

ASHP and the Councils have discussed these issues during a number of Policy Weeks including the challenges of developing a universally accepted evidenced based instrument and database for workload and productivity that includes intensity factors.

The 2013 Council on Pharmacy Management assessed ASHP's policies and past work completed on these issues. The Council felt ASHP's policies were adequate but did vote on additional actions for ASHP's consideration which have been actively worked on. (Information is below).

ASHP and the ASHP Foundation have been working on the development of an instrument that would capture both productivity and complexity for pharmacy. The ASHP Foundation executed a substantial research grant on the development of a complexity instrument that bore evidenced based correlation for pharmacist work vs. patient care outcomes on a limited number of disease states. ASHP convened an expert panel to review industry based information and opportunities to improve and/or develop a product that would integrate ideal components to most accurately demonstrate pharmacist productivity, impact of intensity, and reflect patient care outcome value.

ASHP and the ASHP Foundation will continue its efforts on the aforementioned and this will be supplemented by continued education and advocacy to support our members. An upcoming effort on the education front is a workshop at the Conference for Pharmacy Leaders being led by Steve Rough and Phil Brummond titled: Extended Breakout 3 — Benchmarking and Productivity: Leveraging Data to Drive Results.

Generational Leadership Steering Committee (Recommendation): John Hertig, Dan Degnan, Amy Hyduk (IN)

Recommend that ASHP move forward with establishing a leadership steering committee to explore leadership development needs for different generations of pharmacists.

ASHP is interested in further exploration of this topic to identify, query, and learn about generational differences as it relates to diverse member needs. We will be pursuing activity in this area in the coming year.

Responsible Prescribing and Use of Medications with Abuse Potential (Recommendation): Michael Dickens, Elizabeth Duncan, Diane Fox (ID, TX)

We recommend that ASHP, in cooperation with stakeholders at the federal and state level, develop evidence-based prescribing and fully fund prescription monitoring programs (PMPs) throughout all states relating to all medications with abuse potential (i.e., opiate analgesics, sedative hypnotics, skeletal muscle relaxants, stimulants, anxiolytics).

The Council on Pharmacy Practice developed a policy related to prescribing of excess medications in 2016. This policy, Reduction of Unused Prescription Drug Products, was approved by the March 2017 virtual House of Delegates. CPhP thought it was prudent to address all medications, even though opioids are the emphasis. Excess quantities can lead to abuse either by the patient, or those who have access to the patient's prescriptions. In addition, ASHP continues to work with external agencies, as well as an internal ASHP taskforce, to focus on various approaches and tactics for healthcare workers regarding use of medications with abuse potential.

Automation of the "De-Prescribing Process" (Recommendation): Gregory P. Burger, Joan Kramer (KS, IL, IN, WI, AK, TX, WA, SOPIT)

ASHP should advocate for electronic prescribing systems to require automation of the de-prescribing process by two-way communication ability to discontinue, stop, or cancel electronic prescriptions (and for retail pharmacies to receive and manage this information).

ASHP agrees with the concept and action of "de-prescribing" and is investigating approaches by various states. This work is also tied to the national coalition group focusing on indication-based prescribing. The "how" of this still remains elusive for some states and the idea will be further explored with the ASHP Section on Pharmacy Informatics and Technology.

Waiver of Summer Meeting Registration Fees for Voting House of Delegate Attendees (Recommendation): Paul Goebel, President, NJSHP (NJ)

We request that the ASHP Board of Directors explore a waiver for the regular registration fee for voting House of Delegates attendees to the ASHP Summer Meetings.

During their September 2015 meeting, the ASHP Commission on Affiliate Relations discussed a variety of ways that ASHP could support House of Delegate activities, including adjusting the delegate stipend process. Their discussion considered Summer Meeting registration fees. The Commission concluded that increasing the delegate stipend would be the most efficient method to provide additional support for each state's delegates. Therefore, for 2017, ASHP will be adjusting the stipend amount provided to support each delegation and will evaluate this support on an ongoing basis. The Commission requested that ASHP continue to collect best practices around delegate issues by surveys of members and state organizations and to share this information on a regular basis.

ASHP Working with NASPA (Recommendation): Dan Degnan (IN)

That ASHP actively participate in the activities of the National Alliance of State Pharmacy Associations (NASPA) as a method to support ASHP state affiliates.

To meet the needs of all state affiliates, ASHP is focused on participating in partnerships that represent a continuum of pharmacy practice within the healthcare environment. To the extent possible, ASHP

endeavors to participate in meetings with other state and national pharmacy organizations. ASHP works with NASPA as a member of the Joint Commission of Pharmacy Practitioners, the Pharmacy Health Information Technology Collaborative, the Pharmacy Quality Alliance, and the Patient Access to Pharmacists' Care Coalition. ASHP regularly collaborates with pharmacy associations and other healthcare associations on coalitions and stakeholder groups focusing on critical healthcare issues of mutual interest such as sustainable drug pricing, antimicrobial stewardship, and the opioid and drug abuse crises. ASHP is committed to working with a variety of associations, alliances and coalitions to further our mission.

Pharmacy Technician Membership (Recommendation): Emily Alexander (SICP)

Conduct a workforce survey and work with state affiliates and other organizations to determine best practices and models to increase pharmacy technician membership within ASHP.

Your recommendation is in concurrence with ASHP's membership and professional practice initiatives. The most recent ASHP Task Force on Organizational Structure studied pharmacy technician membership within ASHP. The Task Force recommended that ASHP work to increase technician membership and engage technicians within the Society. The Section of Inpatient Care Practitioners has certainly embraced this recommendation of which is appreciated. In addition, ASHP has offered its subscription-based CE service designed specifically to meet the educational needs of pharmacy technicians, pharmtechve.org, at no additional fee for technician members. State affiliates of ASHP that co-market this product will receive a portion of the subscription revenue. In the near future, ASHP plans to study pharmacy technician needs which we hope will increase technician membership and engagement at the state and national level.

ASHP worked with PTCB recently to conduct a pharmacy technician workforce study. The final results have not yet been published we will provide you and the SICP with some of the key findings as soon as possible so that you can factor this into your SAG and EC discussions. ASHP will conduct a webinar for our state affiliates so that they are also aware of the key findings.

Standardization of IV Push Medications: Concentrations, Rate, and Terminology (Recommendation): Gregory P. Burger (KS, IN, WS, TX, WA)

ASHP should collaborate with professional organizations, accrediting bodies, and other stakeholders to determine and standardize optimal IV push rates, concentrations, and terminology for IV push medications.

ASHP continues to work with ISMP on this effort. In addition, the Standardize 4 Safety initiative will be tackling the standardization of intermittent IV medications in late 2017. Rates and terminology need to be heavily vetted with nursing organizations and will take a significant amount of time before decisions can be made, but ISMP, FDA, and ASHP do consider this a priority.

Evidence-based Policies, Guidelines, and Recommendations (Recommendation): Jeff Wagner (TX)

Advocate that recommendations of regulatory and healthcare related organizations are based on rigorous objective evidence and systematic review of available research.

ASHP has worked extensively with the FDA and TJC within the last year and provided lengthy comments and raised concerns about the implementation of USP Chapter 800. ASHP has been working with publishing on the release of a book related to Chapter 800, in addition to the creation of a sterile compounding certificate. More resources can be found at: <https://www.ashp.org/search?q=Chapter%20800>

Ongoing and Consistent Information Exchange Among State Boards of Pharmacy (Recommendation): Christi Jen, Carol Rollins, Melinda Burnworth (AZ)

To advocate that all state boards of pharmacy maintain ongoing and real-time/expedited information exchange regarding status of their licensees for reciprocity, particularly on disciplinary action.

Since the House of Delegates passed policy this year on streamlining licensing of pharmacists by state boards, the next step is to begin advocating for faster licensing of pharmacists, especially residents who may only be in that state/jurisdiction for the term of residency. One item ASHP is considering is to explore creating a multi-state compact where states could enter into licensing agreements with other states for

pharmacists who practice in multiple states (e.g., telepharmacy). The multi-state compact could include a database that contains up-to-date information on the status of each pharmacist licensed. As such, any change in the status would be applicable throughout the compact. Nursing has such an arrangement and 25 states are already a part of it. This may help alleviate the delay and improve disciplinary issue awareness. ASHP is planning to reach out to NABP to explore such a compact and the timeliness of licensing status would certainly be a part of that.

Another approach is to ask the Council on Public Policy to go back and include the language in the recommendation: to advocate that all state boards of pharmacy maintain ongoing and real-time information exchange regarding the status of their licenses for reciprocity, particularly on disciplinary action.

E-Prescribing and CDTM (Recommendation): Adam Porath (NV)

Recommend that ASHP advocate that state laws and regulations concerning e-prescribing consider pharmacists CDTM protocols.

As part of the annual sunset review process, the Council on Public Policy reviews its policies to determine whether the policy is still relevant, whether it needs to be updated, or whether the policy should no longer exist. ASHP's policy 1217 on Collaborative Drug Therapy Management is due for sunset review and the Council on Public Policy will be updating it to include e-prescribing and HIT systems. Council members overwhelmingly agreed that this is a relevant and timely suggestion as states are updating their CDTM laws and regulations. We expect that ASHP policy will be updated to include the suggestion you made during the House of Delegates 2016 Summer Meeting.

Pharmacist Prescribing of Naloxone (Recommendation): John Pastor (MN)

That ASHP advocate with Boards of Pharmacy to allow pharmacists to prescribe naloxone to expand access to this lifesaving medication.

The Council on Therapeutics developed policy in 2015 that specifically supports efforts to enable pharmacists to prescribe naloxone.

Naloxone Availability (1510)

Source: Council on Therapeutics

To recognize the potential public health benefits of naloxone for opioid reversal; further,

To support efforts to safely expand access to naloxone; further,

To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone after receiving education; further,

To foster education on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care; further,

To support state efforts to authorize pharmacists' prescribing authority for naloxone for opioid reversal.

Timely Board of Pharmacy Licensing (Recommendation): Daniel M. Ashby, (ASHP Past President, MD)

The Council on Public Policy should review additional options to address timely licensure by state Boards of Pharmacy including but not limited to strategies used by other professions including the Nursing License Compact, now a 25-state program supporting a single license.

The recommendations entitled Timely Board of Pharmacy Licensing and ASHP to Explore a Standardized Framework for Licensure and Credentialing Nationally are similar in nature, with one of them calling for a national licensing framework, and the other urging pharmacy to explore a multi-state compact similar to nurses who have created such a compact in which 25 states currently participate. ASHP believes that the policy language recently adopted is broad enough to allow for any number of arrangements that would reduce the delays in obtaining a pharmacy license. ASHP believes our policy adequately covers the recommendations, but there are action steps that ASHP can and is taking to address the problem.

The Council on Public Policy in 2015 developed policy that calls upon NABP to work with state boards to streamline the licensure process, allows for license reciprocity, and advocates that state boards grant temporary licensure to pharmacists who are seeking reciprocity from another state when their license is in good standing. This is a direct result of increasing delays in obtaining a pharmacy license in a new state and is particularly problematic for residents who move from one state to another.

ASHP is in the process of exploring such a licensing compact with NABP. For example, ASHP has undergone outreach to the NABP district meeting organizers to offer our help in the way of presenting key health system pharmacy issues at the district meetings which are typically held in the fall. One of the topics we are proposing is to discuss the licensing issue and delays that are problematic for residents. In addition, if there is an opportunity for us to discuss further at NABP's national meeting, we will certainly be talking about it. Finally, this issue and how we approach it would be a relevant topic at our Mid-Year Clinical Meeting of ASHP members who serve on state boards of pharmacy. This may help us map out a strategy to address the problem. While ASHP has no official position over a national licensing framework versus the state compact, the latter may be an easier lift politically given states' reluctance to relinquish their authority as part of a national effort. The multi-state compact may allow for greater flexibility and faster licensing processes while not being viewed as a threat to state sovereignty.

In short, ASHP believes that this remains a significant problem and while our policy may address it, action by the Society is needed in the way of advocacy to create a more efficient and streamlined licensing process.

Regarding the question on a nationwide credentialing process, the Council on Credentialing (CoC) is exploring ways in which this process may be improved. As states (and potentially the federal government) begin to recognize pharmacists as patient care providers, payers will be looking at developing pharmacy networks, and early experience in a few states suggests that the credentialing process in hospitals is a good start. This issue will only gain in importance, especially if pharmacists become able to participate in the Medicare program. ASHP staff who interface with the CoC is aware of this suggestion and will take it into consideration.

Enhancing the U.S. Public Health Efforts in Health Promotion through Public-Private Collaboration (Recommendation): Steve Riddle (WA, KS, AL, OR)

To encourage ASHP to engage the FDA, office of the CDC related to public health, healthcare professional organizations (e.g., AMA, APhA) and notable commercial healthcare entities that produce medications and other treatment modalities (e.g., pharmaceutical manufacturers, biomedical companies) to explore enhancements to public health awareness and education system including funding to support identified improvements.

Based upon the background of this recommendation, ASHP may consider developing new policy by the Council on Public Policy or begin a dialogue with AMA to gauge the physician community position on this issue.

Updates on actions taken on your recommendation will be posted on the House of Delegates section of the ASHP website. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Update Statement on Cultural Diversity to Explicitly Include the LGBT in the Statement (Recommendation): Tim Brown (ASHP Board Member)

[Update statement on cultural diversity to explicitly include LGBT in the statement.](#)

The Council on Education and Workforce Development will address your recommendation during Policy Week in September 2016. Your recommendation will be posted on the House of Delegates section of the ASHP website and published in the House of Delegates Proceedings. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Policy 9820 Update (Recommendation): Curtis Collins (SCSS)

Recommendation: Update Policy 9820 Medication Administration by Pharmacists to advocate for changes in state practice acts to include pharmacist administration of all medications.

There are many aspects associated with IV medications (ordering, compounding, dispensing, administration), and ASHP is currently trying to prioritize what areas need to be addressed first. Given the recent climate of errors associated with sterile compounding, ASHP has prioritized this work to be tackled first, and then emphasis on other stages of the IV medication life-cycle will follow.

Safety of Compounded Products (Recommendation): Brian I. Kawahara (CA)

Recommendation: ASHP should look to expand the ideas presented in the Safety of Epidural Steroid Injection policy to include those products (medications and diagnostic agents) that are being used or compounded with little evidence to support their efficacy or safety (e.g., radiologic mixed together or with food). Patients should be informed about: the risks and benefits of using, combining, or administering agents in a manner; and proven or lower risk alternative.

The Council on Pharmacy Practice agrees the policy Safety of Epidural Steroid Injections should be more inclusive and it is currently under review.

ASHP to Explore a Standardized Framework for Licensure and Credentialing Nationally (Recommendation): Julie Groppi, Mary Parker, Katelyn Dervay (Veterans Affairs, NC, FL)

Through partnership with NABP and State Board of Pharmacy, ASHP should explore development of a standardized framework for licensure and credentialing of pharmacists nationally.

The recommendations entitled Timely Board of Pharmacy Licensing and ASHP to Explore a Standardized Framework for Licensure and Credentialing Nationally are similar in nature, with one of them calling for a national licensing framework, and the other urging pharmacy to explore a multi-state compact similar to nurses who have created such a compact in which 25 states currently participate. ASHP believes that the policy language recently adopted is broad enough to allow for any number of arrangements that would reduce the delays in obtaining a pharmacy license. ASHP believes our policy adequately covers the recommendations, but there are action steps that ASHP can and is taking to address the problem.

The Council on Public Policy in 2015 developed policy that calls upon NABP to work with state boards to streamline the licensure process, allow for license reciprocity, and advocate that state boards grant temporary licensure to pharmacists who are seeking reciprocity from another state when their license is in good standing. This is a direct result of increasing delays in obtaining a pharmacy license in a new state and is particularly problematic for residents who move from one state to another.

ASHP is in the process of exploring such a licensing compact with NABP. For example, ASHP has undergone outreach to the NABP district meeting organizers to offer our help in the way of presenting key health system pharmacy issues at the district meetings which are typically held in the fall. One of the topics we are proposing is to discuss the licensing issue and delays that are problematic for residents. In addition, if there is an opportunity for us to discuss further at NABP's national meeting, we will certainly be talking about it. Finally, this issue and how we approach it would be a relevant topic at our Mid-Year Clinical Meeting of ASHP members who serve on state boards of pharmacy. This may help us map out a strategy to address the problem. While ASHP has no official position over a national licensing framework versus the state compact, the latter may be an easier lift politically given states' reluctance to relinquish their authority as part of a national effort. The multi-state compact may allow for greater flexibility and faster licensing processes while not being viewed as a threat to state sovereignty.

In short, ASHP believes that this remains a significant problem and while our policy may address it, action by the Society is needed in the way of advocacy to create a more efficient and streamlined licensing process.

Per the question on a nationwide credentialing process, the Council on Credentialing is exploring ways

in which this process may be improved. As states (and potentially the federal government) begin to recognize pharmacists as patient care providers, payers will be looking at developing pharmacy networks, and early experience in a few states suggests that the credentialing process in hospitals is a good start. This issue will only gain in importance, especially if pharmacists become able to participate in the Medicare program. ASHP staff who interface with the CoC is aware of this suggestion and will take it into consideration.

Updates on actions taken on your recommendation will be posted on the House of Delegates section of the ASHP website. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Consolidate Similar Policies (Recommendation): Carol Rollins (AZ)

Consolidate policies for individual drugs/drug classes into a single policy when the activities within the individual policies are consistent with general pharmacy activities.

ASHP councils often identify specific practice gaps that they wish to highlight in ASHP policy, which sometimes results in redundancies. ASHP's Councils, Sections, and Forums will continue to seek opportunities to combine like policies, and remove redundancies when indicated. Your recommendation has been posted on the House of Delegates section of the ASHP website and published in the House of Delegates Proceedings. Next year's June meeting of the House will receive an update on actions taken by ASHP in response to the recommendation.

Culturally and Ethnically Diverse Workforce (Recommendation): Diane Fox, Jen Phillips, Joan Kramer (TX, IL, KS)

The Council on Education and Workforce Development should develop a policy advocating for an ethnically diverse workforce.

The Council on Education and Workforce Development will address your recommendation during Policy Week in September 2016. Your recommendation will be posted on the House of Delegates section of the ASHP website and published in the House of Delegates Proceedings. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Interstate Patient-Specific Pharmacists Cognitive (Non-dispensing) Service Practice (Recommendation): Steven Gray (CA)

Form a task force to study and make recommendations to resolve the barriers to interstate patient-specific cognitive services practice.

In response to the state licensing issue and streamlining the process, ASHP may approach NABP about forming a multi-state licensing compact. The nursing profession currently has it which may not only aid in terms of obtaining a license faster, but could also help establish certain ground rules to recognize the level of care pharmacists in other states could provide. This could also be important from a telepharmacy perspective as folks in one state may be receiving care from a pharmacist in another.

Updates on actions taken on your recommendation will be posted on the House of Delegates section of the ASHP website. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Partnership Between ASHP and State Affiliates to Provide BPS Continuing Education (Recommendation):

Ryan Miller (WI, AZ, MO, OH, VT, NC, IL, CT, MT, NV, CO, MA, IA, TN, PA, MN, OR, TX, UT, ME, KS, CA, OK, WA, MI, MS)

ASHP has spent considerable time exploring the concept you have recommended and has learned through this exploration that it is challenging to expand at the state and regional level. Planning and conducting BPS recertification activities is a complex process and one not easily localized.

ASHP has engaged with each state affiliate president and/or affiliate staff to explain these challenges and remain open to any options, proposals, and business plans that are feasible for a state and national

partnership.

Your recommendation will be posted on the House of Delegates section of the ASHP website and published in the House of Delegates Proceedings. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Consider Indianapolis as a Location for ASHP Summer Meetings (Recommendation): Dan Degnan, John Hertig, Amy Hyduk (IN, WA, MO, CA, MN, CT, WI, ME, ID, SD, UT, MA, OH, IA, VA, IL, MS, NH, PR, FL, MI, NPF, PSF, SICP)

That ASHP consider Indianapolis, host of Super Bowl 46 and the largest one day sporting event in the world, as a host city for the Summer Meetings.

ASHP understands the importance of rotating the host city of our various meetings, conferences, and specialty courses each year. I want to assure you that ASHP will explore the potential viability of this venue for one of our meetings. Several criteria are considered in selecting a location and we must keep the following 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

Your recommendation will be posted on the House of Delegates section of the ASHP website and published in the House of Delegates Proceedings. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Edit Policy 1608 on Adding Indications to Provider Orders/Prescriptions (Recommendation): Gregory Burger (KS)

Edit out "clinical decision support." Edit in "entire medication use process." Forty-six percent of the House of Delegates thought the language was fuzzy. What will our membership think? Most are not IT folks and will not understand clinical decision support will include prescribing process.

The Council on Therapeutics has considered this recommendation and had decided to take no action at this time.

Your recommendation will be posted on the House of Delegates section of the ASHP website and published in the House of Delegates Proceedings. Next year's session of the House will receive an update on actions taken by ASHP in response to the recommendation.

Professional Policies Approved by the 2017 ASHP House of Delegates

Appendix XIII

Minneapolis, MN

June 6, 2017

Am J Health-Syst Pharm. 2017; 74:e430-4

The new professional policies approved by the ASHP House of Delegates are listed below. Policies 1701–1703 were approved by the virtual House of Delegates in March. Policies 1704–1725 were approved at the June meetings of the House of Delegates. 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 “House of Delegates,” and then on “Action Items,” and then on “Board of Directors Reports on Councils.” (<https://www.ashp.org/House-of-Delegates/HOD-Session-Information/Action-Items>)

The complete proceedings of the House of Delegates will be provided to delegates and will be posted on the ASHP Web site.

1701

Ensuring Patient Safety and Data Integrity During Cyber-attacks

Source: Council on Pharmacy Management

To advocate that healthcare organizations include pharmacists in (1) assessing cyber-security systems and procedures for vulnerabilities, (2) implementing cyber-security strate-

gies, and (3) reviewing cyber-security breaches and developing corrective actions; further,

To encourage the development of business continuity plans by pharmacy departments; further,

To advocate that healthcare organizations assess vendor systems to validate the security and integrity of data, including an assessment of the minimum amount of patient health information vendors require to provide services.

1702

Reduction of Unused Prescription Drug Products

Source: Council on Pharmacy Practice

To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,

To advocate for research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, including but not limited to partial fills or refills; further,

To advocate that pharmacists take a leadership role in reducing excess quantities of unused prescription drug products.

1703

Pharmacist's Leadership Role in Anticoagulation Therapy Management

Source: Council on Therapeutics

To advocate that pharmacists provide leadership in caring for patients receiving medications for anticoagulant therapy management; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications for anticoagulation therapy management; further,

To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

This policy supersedes ASHP policy 0816.

1704

Medical Aid in Dying

Source: Board of Directors

To affirm that a pharmacist's decision to participate or decline to participate in medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To take a stance of studied neutrality on legislation that would permit medical aid in dying for competent, terminally ill patients.

This policy supersedes ASHP policy 9915.

1705

Workforce Diversity

Source: Council on Education and Workforce Development

To affirm that a diverse and inclusive workforce contributes to health equity and health outcomes; further,

To advocate for the development of a workforce whose background, perspectives, and experiences reflect the diverse patients for whom pharmacists provide care.

1706

ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process

Source: Council on Education and Workforce Development

To encourage all educators of the pharmacy workforce to use ASHP statements, guidelines, and professional policies as an integral part of education and training.

This policy supersedes ASHP policy 0705.

1707

Pharmaceutical Distribution Systems

Source: Council on Pharmacy Management

To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To oppose manufacturers, distributors, and wholesalers making availability of drug products contingent on how those products are used.

This policy supersedes ASHP policy 1016.

1708

Mobile Health Tools, Clinical Apps, and Associated Devices

Source: Council on Pharmacy Management

To advocate that patients, pharmacists, and other healthcare professionals be involved in the selection, approval, and management of mobile health tools, clinical software applications (“clinical apps”), and associated

devices used by clinicians and patients for patient care; further,

To foster development of tools and resources to assist pharmacists in designing and assessing processes to ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices; further,

To advocate that decisions regarding the selection, approval, and management of mobile health tools, clinical apps, and associated devices should further the goal of delivering safe and effective patient care and optimizing outcomes; further,

To advocate that mobile health tools, clinical apps, and associated devices that contain health information be interoperable and, if applicable, be structured to allow incorporation of health information into the patient’s electronic health record and other essential clinical systems to facilitate optimal health outcomes; further,

To advocate that pharmacists be included in regulatory and other evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management.

1709

Controlled Substance Diversion Prevention

Source: Council on Pharmacy Management

To encourage healthcare organizations to develop controlled substances diversion prevention programs and policies that delineate the roles, responsibilities, and oversight of all personnel who have access to controlled substances to ensure compliance with applicable laws and scopes of practice; further,

To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and surveillance, auditing, and monitoring are conducted on an ongoing basis to support a safe patient-care environment, protect co-

workers, and discourage controlled substances diversion.

1710

Revenue Cycle Compliance and Management

Source: Council on Pharmacy Management

To encourage pharmacists to serve as leaders in the development and implementation of strategies to optimize medication-related revenue cycle compliance, which includes verification of prior authorization, patient portion of payment, billing, reimbursement, and financial documentation for the healthcare enterprise; further,

To advocate for the development of consistent billing and reimbursement policies and practices by both government and private payers; further,

To advocate that information technology (IT) vendors enhance the capacity and capability of IT systems to support and facilitate medication-related purchasing, billing, and audit functions; further,

To investigate and publish best practices in medication-related revenue cycle compliance and management.

This policy supersedes ASHP policy 1205.

1711

Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use

Source: Council on Pharmacy Practice

To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that regulators (e.g., the Food and Drug Administration) have the authority to impose requirements on pharmaceutical manufacturers to provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacies repackage those drug products to minimize the risk of exposure; further,

To advocate that hazardous drug products intended for home use be labeled to warn that special handling is required for safety; further,

To advocate that pharmacists provide education to patients and caregivers regarding safe handling and appropriate disposal of hazardous drug products intended for home use.

1712

Expiration Dating of Pharmaceutical Products

Source: Council on Pharmacy Practice

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures to encourage pharmaceutical manufacturers to readily update expiration dates, for as long as possible while maintaining drug potency and safety, to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

This policy supersedes ASHP policy 9309.

1713

Partial Filling of Schedule II Prescriptions

Source: Council on Public Policy

To advocate that state legislatures and boards of pharmacy create consistent laws and rules to allow partial filling of Schedule II drugs; further,

To advocate that public and private entities construct criteria for partial filling to minimize the additional burden on patients, pharmacists, and healthcare organizations; further,

To advocate that pharmacists educate prescribers and patients about options for filling prescriptions for Schedule II drugs, including the risks of overprescribing, while recognizing the patient or caregiver's rights to make their own care and management decisions.

1714

Restricted Drug Distribution

Source: Council on Public Policy

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

This policy supersedes ASHP policy 0714.

1715

Collaborative Practice

Source: Council on Public Policy

To pursue the development of federal and state laws and regulations that authorize pharmacists as providers within collaborative practice; further,

To advocate expansion of federal and state laws and regulations that optimize pharmacists' ability to provide the full range of professional services within their scope of expertise; further,

To advocate for federal and state laws and regulations that would al-

low pharmacists to prescribe and transmit prescriptions electronically; further,

To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication related outcomes; further,

To support affiliated state societies in their pursuit of state-level regulations allowing collaborative practice for pharmacists.

This policy supersedes ASHP policy 1217.

1716

Greater Competition Among Generic and Biosimilar Manufacturers

Source: Council on Public Policy

To advocate for legislation and regulations that promote greater competition among generic and biosimilar pharmaceutical manufacturers.

This policy supersedes ASHP policy 0222.

1717

Drug Testing

Source: Council on Public Policy

To recognize the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

This policy supersedes ASHP policy 9103.

1718

Therapeutic and Psychosocial Considerations of Transgender Patients

Source: *Council on Therapeutics*

To support medication and disease management of transgender patients as a part of care unique to this population; further,

To advocate that transgender patients have access to pharmacist care to ensure safe and effective medication use; further,

To promote research on, education about, and development and implementation of therapeutic and biopsychosocial best practices in the care of transgender patients; further,

To encourage structured documentation of both a patient's birth sex and self-identified gender in electronic health records.

1719

Pharmacist's Leadership Role in Glycemic Control

Source: *Council on Therapeutics*

To advocate that pharmacists provide leadership in caring for patients receiving medications for management of blood glucose; further,

To advocate that pharmacists be a member of the interprofessional healthcare team that coordinates glycemic management programs; further,

To encourage pharmacists who participate in glycemic management to educate patients, caregivers, prescribers, and other members of the healthcare team about glycemic control medication uses, metrics, drug interactions, adverse effects, lifestyle modifications, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

1720

Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics

Source: *Council on Therapeutics*

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions; further,

To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.

1721

Clinical Significance of Accurate and Timely Height and Weight Measurements

Source: *Council on Therapeutics*

To encourage pharmacists to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,

To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting

and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes.

1722

Pain Management

Source: *Council on Therapeutics*

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 foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects; further,

To encourage the education of pharmacists, pharmacy students, and other healthcare providers regarding the principles of pain management and substance abuse that encourage holistic, supportive approaches and reduce stigma surrounding opioid-use disorders.

This policy supersedes ASHP policy 1106.

1723**Clinical Investigations of Drugs Used in Elderly and Pediatric Patients***Source: Council on Therapeutics*

To advocate for increased enrollment and outcomes reporting of pediatric and geriatric patients in clinical trials of medications; further,

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric and geriatric patients to facilitate safe and effective dosing of medications in these patient populations.

This policy supersedes ASHP policy 0229.

1724**Safe and Effective Therapeutic Use of Invertebrates***Source: Council on Therapeutics*

To recognize use of medical invertebrates as an alternative treatment in limited clinical circumstances; further,

To educate pharmacists, patients, and the public about the risks and benefits of medical invertebrates use and about best practices for use; further,

To advocate that pharmacy departments, in cooperation with other departments, provide oversight of medical invertebrates to assure appropriate formulary consideration and safe procurement, storage, control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, and disposal; further,

To encourage independent research and reporting on the therapeutic use of medical invertebrates.

1725**Drug Dosing in Extracorporeal Therapies***Source: Council on Therapeutics*

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To collaborate with stakeholders in enhancing aggregation of data on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To encourage the education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing in extracorporeal therapies.

This policy supersedes ASHP policy 1606.