



House of Delegates Session—2018

June 3 and 5, 2018
Denver, Colorado

Proceedings of the 70th annual session
of the ASHP House of Delegates,
June 3 and 5, 2018

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Paul W. Abramowitz, Secretary

The 70th annual session of the ASHP House of Delegates was held at the Colorado Convention Center, in Denver, Colorado, in conjunction with the 2018 Summer Meetings.

First meeting

The first meeting was convened at 1:00 p.m. Sunday, June 3, by Chair of the House of Delegates Amber J. Lucas. Chair Lucas introduced the persons seated at the head table: Lisa M. Gersema, Immediate Past President of ASHP and Vice Chair of the House of Delegates; Paul W. Bush, 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 201 delegates representing 49 states and the District of Columbia (no delegates from Hawaii), 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 69th 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 69th House of Delegates session were received without objection.

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

President 2019–2020

Kathleen S. Pawlicki, M.S., B.S.Pharm., R.Ph., FASHP, Vice President and Chief Pharmacist, Beaumont Health, Warren, MI

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

Board of Directors, 2018–2021

Kristina (Kristy) L. Butler, B.S. Pharm., Pharm.D., BCACP, FASHP, FOSHPP, Manager, Clinical Pharmacy Specialists, Providence Medical Group - Oregon Region Providence St. Joseph Health, Portland, OR

Nishaminy Kasbekar, B.S., Pharm.D., FASHP, Director of Pharmacy, Penn Presbyterian Medical Center, Philadelphia, PA

Pamela K. Phelps, Pharm.D., R.Ph., FASHP, Director, Fairview Health Services, Minneapolis, MN

Jamie S. Sinclair, B.S. Pharm., M.S., RPh, FASHP, Director, Pharmacy Services, Mercy Medical Center, Cedar Rapids, IA

Chair, House of Delegates, 2018–2020

Melanie A. Dodd, Pharm.D., Ph.C., BCPS, FASHP, Department Vice-Chair and Associate Professor Department of Pharmacy Practice and Administrative Sciences, The University of New Mexico College of Pharmacy, Albuquerque, NM

Casey H. White, Pharm.D., M.B.A., BCPS, BCNSP, BCCCP, FASHP, Director of Pharmacy, Cookeville Regional Medical Center, Cookeville, TN

A “Meet the Candidates” session to be held on Monday, June 4, was announced. Chair Lucas announced the candidates for the executive committees of the five sections of ASHP.

Policy committee reports. Chair Lucas outlined the process used to generate policy committee reports (Appendix III). 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: underlined type indicates material added; ~~strikethrough~~ marks indicate material deleted. If no amendments are noted, the policy as proposed was adopted by the House. For purposes of this report, no distinction has been made between formal amendments and wording suggestions made by delegates.*

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

Lea S. Eiland, Board Liaison to the **Council on Pharmacy Management**, presented the Council’s Policy Recommendations 1 through 6.

1. Medication Formulary System Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; and (3) should not be based solely on economic factors.

This policy supersedes ASHP policy 0102.

***2. Manufacturer-sponsored Patient Assistance Programs**

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

To advocate expansion of PAPs to include high-cost drug products used in inpatient settings; further, [MOVED FROM BELOW]

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

To advocate expansion of PAPs to include high-cost drug products used in inpatient settings; further, [MOVED ABOVE]

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and visibility of PAPs to pharmacy personnel and other members of the healthcare providers team; further,

To encourage pharmacists, other patient care providers, pharmacy personnel, other healthcare providers, and pharmaceutical manufacturers to work cooperatively to ensure PAPs include the that essential elements of pharmacist patient care, are patient-centered, and are transparent are included in these programs; further,

To develop education for pharmacists pharmacy personnel and other healthcare providers on the risks and benefits of PAPs.

(Note: This policy would supersede ASHP policy 1420.)

***3. ~~Product~~ Reimbursement and Pharmacist Compensation for Drug Product Dispensing** (title changed to reflect revised text)

To collaborate with ~~public and private~~ payers in developing improved methods of reimbursing pharmacies and pharmacists for the costs of drug products dispensed, pharmacy and pharmacist services (e.g., ~~compounding, dispensing, drug product administration, patient monitoring, and patient education~~), and associated overhead; further,

To educate pharmacists and stakeholders about those methods.

(Note: This policy would supersede ASHP policy 1304.)

***4. Patient Access to Pharmacist Care Within Provider Networks**

To advocate for laws and regulations that would require healthcare payers, when creating provider networks, to include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits when delivered by other healthcare providers; further,

To advocate for laws and regulations that ~~would~~ allow a pharmacists and pharmacy or pharmacies ~~to~~ participate as a provider within a healthcare payer’s network if the pharmacist or pharmacy meets the payer’s criteria for providing those healthcare services; further,

To acknowledge that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality and viability of healthcare services provided; further,

To advocate that healthcare payers be required to disclose to pharmacists and pharmacies applying to participate in a provider network the criteria used to include, retain, or exclude pharmacists or pharmacies.

5. Health Insurance Policy Design

To advocate that all health insurance policies be designed and coverage decisions made in a way that preserves the patient-practitioner relationship; further,

To advocate that health insurance payers and pharmacy benefit managers provide public transparency regarding and accept accountability for coverage decisions and policies; further,

To oppose provisions in health insurance policies that interfere with established drug distribution and clinical services designed to ensure patient safety, quality, and continuity of care; further,

To advocate for the inclusion of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

This policy supersedes ASHP policy 1520.

6. Pharmacy Accreditations, Certifications, and Licenses

To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,

To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidenced-based principles of patient safety and quality of care; further,

To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,

To advocate that health-system administrators, including compliance officers and risk managers, allocate the resources required to support medication-use compliance and regulatory demands.

This policy supersedes ASHP policy 1303.

Todd A. Karpinski, Board Liaison to the **Council on Pharmacy Practice**, presented the Council's Policy Recommendations 1 through 4.

***1. Use of International System of Units for Patient-related Measurements**

To advocate that the U.S. healthcare system adopt and only use the International System of Units (SI units) for all patient and medication-related measurements and calculations; further,

To advocate that healthcare organizations use clinical decision support systems, and equipment, and devices that allow input and display of patient and medication-related measurements and calculations in SI format only; further,

To advocate that health information technology manufacturers utilize only SI units in their product designs for patient and medication-related measurements; further,

To promote education in the use of SI units and the importance of using SI units to prevent medical errors.

***2. Availability and Use of Appropriate Vial Sizes**

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste and enhance safety (e.g., multiple-dose vials or single-dose vials of differing doses); further,

To collaborate with regulators, manufacturers, and other health-care providers to develop best practices on the safe and appropriate use of single-dose, single-use, and multiple-dose vials.

***3. Use of Closed-System Transfer Devices to Reduce Drug Waste**

To recognize that peer-reviewed a growing body of evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used with aseptic technique and following current sterile compounding standards; further,

To foster additional research on and develop standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

4. Collaborative Drug Therapy Management

To discontinue ASHP policy 9801, which reads:

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

To recognize that pharmacists participate in collaborative drug therapy management for a patient who has a confirmed diagnosis by an authorized prescriber; further,

To recognize that the activities of a pharmacist in collaborative drug therapy management may include, but not be limited to, initiating, modifying, and monitoring a patient's drug therapy; ordering and performing laboratory and related tests; assessing patient response to therapy; counseling and educating a patient on medications; and administering medications.

Timothy R. Brown, Board Liaison to the **Council on Public Policy**, presented the Council's Policy Recommendations 1 through 10.

***1. ASHP Statement on Advocacy as a Professional Obligation** (from second paragraph):

Advocacy can be defined as an activity by an individual or group to plead a case, support a cause, or to recommend a course of action related to patient-care, political, economic, social, or institutional-or patient-care issues.

***2. Direct and Indirect Remuneration Fees**

To advocate that private payers and pharmacy benefit managers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated dispensing claims; further,

To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.

***3. Impact of Drug Litigation Ads on Patient Care**

To oppose drug litigation advertisements that could lead patients to modify or discontinue therapy without consulting their providers; further, To advocate that drug litigation advertisements that may cause patients to discontinue medically necessary drugs be required to do not provide a clear and conspicuous warning that patients should not modify or discontinue drugs therapy without seeking the advice of their healthcare provider.

***4. Approval of Biosimilar Medications (title changed to reflect revised text)**

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

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

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

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

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

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; further,

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

To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA; further,

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

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

(Note: This policy would supersede ASHP policy 1509.)

***5. 340B Drug Pricing Program Sustainability**

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

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate with state Medicaid programs to ensure that reimbursement policies promote 340B program stability; further,

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

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

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

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

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

(Note: This policy would supersede ASHP policy 1407.)

6. Federal Review of Anticompetitive Practices and Price Increases by Drug Product Manufacturers (defeated by House of Delegates)

To strongly oppose anticompetitive practices by drug product manufacturers that adversely affect drug product availability and price; further,

To encourage appropriate federal review of these practices; further,

To advocate that drug product manufacturers be required to provide public notification in advance of significant price increases.

(Note: This policy would supersede ASHP policy 0814.)

7. Federal Quality Rating Program for Pharmaceutical Manufacturers

To advocate that the Food and Drug Administration (FDA) assign quality ratings to pharmaceutical manufacturers based on the quality of their manufacturing processes, sourcing of active pharmaceutical ingredients and excipients, selection of contract manufacturers, and business continuity plans; further,

To advocate that the FDA consider offering incentives for manufacturers to participate in the program.

***8. Intravenous Fluid Manufacturing Facilities as Critical Public Health Infrastructure**

To advocate that federal and state governments recognize intravenous fluid and associated supply manufacturing facilities as critical public health infrastructure.

9. Medical Devices

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

(Note: This policy would supersede ASHP policy 9106.)

10. ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems

To discontinue the ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems.

Stephen F. Eckel, Board Liaison to the **Council on Therapeutics**, presented the Council's Policy Recommendations 1 through 5.

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

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

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

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

To urge advocate that health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure continuity of care and patient access to orphan drug products; further,

To urge advocate federal review to evaluate whether orphan drug status designation is being used inappropriately to receive FDA approval, extend patents, and decrease competition, or limit discounts, thereby reducing patient access.

(Note: This policy would supersede ASHP policy 1413.)

***2. Rational Use of Medications**

To recognize that irrational medication use is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To support and promote evidenced-based prescribing and deprescribing for indication, efficacy, safety, duration, cost, and suitability for the patient; further,

To advocate that pharmacists lead interprofessional efforts to promote the rational use of medications, including engaging in strategies to monitor, detect, and address patterns of irrational medication use in patient populations.

(Note: This policy would supersede ASHP policy 1312.)

***3. Responsible Medication-related Clinical Testing and Monitoring**

To recognize that overuse of clinical testing is an increasingly recognized problem in practice that can leads to unnecessary costs, waste, and patient harm; further,

To encourage pharmacists accountability to and engagement in interprofessional efforts to promote the appropriate but judicious use of clinical testing; and monitoring, assessment of clinical progress, dose adjustment, and discontinuation of medication therapy, where appropriate; further,

To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate use of procedures and test ordering in healthcare systems ordering of medication-related procedures and tests; further,

To promote the use of interoperable health information technology services to support and health information exchanges to decrease unnecessary testing.

***4. Clinical Practice and Application on the Use of Biomarkers**

To promote appropriate, evidence-based use of biomarkers in clinical practice; further,

To encourage research that evaluates the clinical and safety implications of biomarkers in the care of patients and to guide clinical practice; further,

To promote Food and Drug Administration (FDA) approved qualified medication-biomarkers in drug development, regulation, and use in clinical practice; further,

To foster the development of timely and readily available resources about biomarkers and their evidenced based application in practices.

5. Medication Overuse

To discontinue ASHP policy 1312 Medication Overuse, which reads:

To define medication overuse as use of a medication when the potential risks of using the drug outweigh the potential benefits for the patient; further,

To recognize that medication overuse is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To advocate that pharmacists take a leadership role in interprofessional efforts to minimize medication overuse.

Linda S. Tyler, Board Liaison to the **Council on Education and Workforce Development**, presented the Council’s Policy Recommendations 1 through 6.

***1. Clinician Well-being and Resilience**

To affirm that burnout ~~is a systems and practice issue that~~ adversely affects an individual’s well-being and ~~performance, which can lead to negative~~ healthcare outcomes; ~~and to educate pharmacy professionals and key stakeholders on this issue~~; further, [House clause 2]

To acknowledge that the healthcare workforce encounters unique stressors throughout their education, training, and careers that contribute to burnout; further, [House clause 1]

To declare that healthcare workforce well-being and resilience requires shared responsibility among healthcare team members and between individuals and organizations; further,

To encourage ~~individuals individual pharmacists pharmacy professionals and organizations~~ to embrace resilience and well-being as a personal ~~personal mutual~~ responsibility that should be supported by organizational culture that should be supported by organizational culture; further, [House clause 5]

To encourage ~~healthcare educators, employers, and organizations to~~ the development of programs aimed at prevention, recognition, and treatment of burnout, and to support participation in these programs; further, [House clause 4]

~~To advocate that organizations develop and sustain institutional cultures that support the resilience and well-being of pharmacy professionals; further,~~

To ~~foster continued~~ encourage education and research on stress, burnout, and well-being; ~~especially in pharmacy~~; further, [House clause 7]

To collaborate with other professionals and stakeholders to identify effective preventive and treatment strategies at an individual, organizational, and system level; ~~further~~. [House clause 3]

***2. Student Pharmacist Drug Testing**

To advocate for the use of pre-enrollment, random, and for-cause drug testing throughout pharmacy education and ~~prior to~~ pharmacy practice experiences, based on defined criteria with appropriate testing validation procedures; further,

To encourage colleges of pharmacy to develop policies and processes to identify impaired individuals; further,

To encourage colleges of pharmacy to facilitate access to and promote programs for treatment and to support recovery; further,

To encourage colleges of pharmacy to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

3. Collaboration on Experiential Education

To encourage practitioner contributions to pharmacy education; further,

To encourage pharmacists and pharmacy leaders to recognize their professional responsibility to contribute to the development of new pharmacy practitioners; further,

To promote collaboration of experiential teaching sites with the colleges of pharmacy (nationally or regionally), for the purpose of fostering preceptor development, standardization of experiential rotation schedule dates and evaluation tools, and other related matters; further,

To encourage colleges of pharmacy and health systems to define and develop collaborative organizational relationships that support patient care and advance the missions of both institutions in a mutually beneficial manner.

(Note: This policy would supersede ASHP policies 0315 and 0804.)

***4. Promoting the Image of Pharmacists and Pharmacy Technicians**

To promote the professional image of pharmacists and pharmacy technicians ~~who work in acute and ambulatory settings~~ to the general public, public policymakers, payers, other healthcare professionals, and healthcare organization decision-makers; ~~further,~~

~~To provide ASHP information and recruitment materials highlighting opportunities for pharmacy careers in acute and ambulatory settings.~~

(Note: This policy would supersede ASHP policy 0703.)

5. Practice Sites for Colleges of Pharmacy

To discontinue ASHP policy 0315, Practice Sites for Colleges of Pharmacy, which reads:

To encourage practitioner input in pharmacy education; further,

To encourage that institutional and health-system environments be used as sites for experiential training of pharmacy students; further,

To encourage colleges of pharmacy and health systems to define and develop appropriate organizational relationships that permit a balance of patient care and service, as well as educational and research objectives, in a mutually beneficial manner; further,

To include the administrative interests of both the health system and the college of pharmacy in defining these organizational relationships to ensure compatibility of institutional (i.e., health system or university) and departmental (i.e., pharmacy department and department in the college) objectives; further,

To encourage pharmacists and pharmacy leaders to recognize that part of their professional responsibility is the development of new pharmacy practitioners.

***6. Pharmacy Practice Training Models (retitled Pharmacy Training Models)**

To promote pharmacy practice training models that: (1) provide experiential and residency training in interprofessional patient care; (2) use the knowledge, skills, and abilities of student pharmacists and residents in providing direct patient care; (3) promote use of innovative and contemporary the pharmacist layered-learning models; further,

To support the assessment of the impact of these pharmacy practice training models on the quality of learner experiences and patient care outcomes.

(Note: This policy would supersede ASHP policy 1316.)

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 IV).

The meeting adjourned at 5:00 p.m.

Second meeting

The second and final meeting of the House of Delegates session convened on Tuesday, June 5, at 4:00 p.m. A quorum was present.

Report of President and Chair of the Board. President Bush 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 V).

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

Board of Directors duly considered matters. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 5 to “duly consider” the policies amended at the first meeting. Twenty policy recommendations were amended by the House of Delegates and one was defeated. The Board agreed with amendments of 18 of the policies with minor editorial changes to three of the amended policies to increase their clarity or provide consistency with other ASHP policies.

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 Steve Riddle (WA) to introduce the item of New Business, “The Pharmacist Role in Suicide Prevention” (Appendix VII). Following discussion, the item was approved for referral to the Council on Pharmacy Practice. It reads as follows:

The Pharmacist Role in Suicide Prevention

Motion:

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

ASHP convene a broad-based task force of appropriate stakeholders to explore opportunities to enhance suicide awareness and prevention. Stakeholders to be considered are ASHP members, federal pharmacy personnel, state affiliates, colleges/schools of pharmacy, pharmacy professional organizations, pharmacy students, pharmacy residents and non-pharmacy entities. Areas for exploration should include the adoption of training models and tools for suicide screening, detection and intervention as well as the identification of methods for operationalizing suicide prevention strategies in various pharmacy practice and academic settings.

Background:

Suicide is the 10th leading cause of death in the U.S., and the number and rate of suicides are rising.¹ A recent study found that almost 40 percent of people have a healthcare visit within a week prior to their suicide attempt.² Healthcare professionals in all settings, including pharmacists, are in a unique position to notice depression and suicide warning signs in their patients and to intervene early. Unfortunately, healthcare professionals – and student learners, and practitioners in training – are also at a significant risk for suicide. Suicide is a preventable public health issue and understanding the stressors and hopelessness that lead people to consider suicide and connecting them to the appropriate help can save lives. Pharmacy professionals can play an important role in preventing suicide, overdoses and suicide attempts – creating safer homes, schools and work places. Unfortunately, these professionals and the organizations they work within are generally poorly prepared to address this critical issue

Issues related to suicide management are broad in scope and include assessment, detection of at-risk individuals and proper

subsequent management, as well as dealing with the impact of a completed suicide on family, friends, colleagues and coworkers. However, awareness of and identification of persons at risk for suicide along with appropriate referral has been a common first step in this process.

There are currently 9 states (CA, IN, KY, NV, NH, PA, TN, UT, WA) that mandate healthcare professionals (HCPs) undergo training in suicide assessment, treatment, and management.³ As an example of a coordinated effort to address such issues, Washington State launched a state-wide, comprehensive plan to prevent suicide-related deaths. The Washington Department of Health executed a policy mandating training for HCPs and, as of 2017, pharmacists have now been added to this required training list. Pharmacists must complete a one-time training in suicide assessment, treatment, and management. The training for pharmacists includes content related to the assessment of issues related to imminent harm via lethal means. The Washington State Pharmacy Association (WSPA) is now organizing such training for pharmacists.

Examining issues of suicide prevention from the ASHP perspective, the Society has recently focused policy and other organizational efforts on professional well-being and resilience, but no specific actions have been taken around the issue of suicide prevention. There are also no standards in place for the pharmacy residency programs with regard to wellness or the related issue of suicide risks.

Suggested Outcomes:

ASHP can serve as a catalyst to engage affiliates, members, pharmacy organizations, colleges and schools of pharmacy, and other stakeholders to explore best practice models and innovative ideas around the role of pharmacists (and HCPs) in suicide prevention and management. The spread of formal training programs and best practices would be a notable metric for success. Some other recommended outcomes are listed below:

1. Successful initiation of and recommendations from a task force of stakeholders that identify needs and develop strategies for suicide prevention including suicide risk evaluation and intervention training and tools.
2. Creation of residency accreditation standards that address wellness and resiliency and related suicide risks with consideration for education and training of residents, residency program directors and preceptors.
3. Delivery of education on suicide risk and prevention to members at ASHP conferences and other educational forums.

References:

1. National Institute of Mental Health. Suicide Statistics. <https://www.nimh.nih.gov/health/statistics/suicide.shtml> (accessed 4 June 2018).
2. Ahmedani B, Stewart C, Simon G, et al. Racial/Ethnic Differences in Health Care Visits Made Before Suicide Attempt Across the United States. *Medical Care*. May 2018; 53(5):430-435.
3. American Foundation for Suicide Prevention. State Laws: Training for Health Professionals in Suicide Assessment, Treatment and Management. Last Updated 2/5/18. http://afsp.org/wp-content/uploads/2018/02/AFSP_Health-Professional-Issue-Brief-2-5-18.pdf (accessed 4 June 2018).

Recognition. Chair Lucas recognized members of the Board who were continuing in office (Appendix IX). 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 Bush with an inscribed gavel commemorating his term of office. Dr. Bush 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: Mollie A. Scott, Section of Ambulatory Care Practitioners; Audrey R. Kennedy, Section of Clinical Specialists and Scientists; Todd D. Lemke, Section of Inpatient Care Practitioners; Maritza D. Lew, Section of Pharmacy Informatics and Technology; Kristine K. Gullickson, Section of Pharmacy Practice Managers; John Hill, New Practitioners Forum; Judith Lovince, Pharmacy Student Forum; and Barbara Hintzen, Pharmacy Technician Forum. Chair Lucas then recognized the remaining members of the executive committees of sections and forums.

Installation. Chair Lucas then installed Kelly M. Smith as President of ASHP, Julie A. Groppi and Paul C. Walker as members of the Board of Directors (Appendix IX). (See Appendix X for the Inaugural Address of the Incoming President.)

Adjournment. The 70th annual June meeting of the House of Delegates adjourned at 6:00 p.m.

^aThe Committee on Nominations consisted of John Pastor, Chair (MN); John Armitstead, Vice Chair (FL); Kimberly Benner (AL); Steven Riddle (WA); Meghan Swarthout (MD); David Weetman (IA); and Lanita White (AR).

DELEGATES to the 2018 Session of the House

OFFICERS OF THE HOUSE

Amber Lucas, *Chair*
Paul Bush, *Vice Chair*
Paul Abramowitz, *Secretary*

OFFICERS AND BOARD OF DIRECTORS

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

PAST PRESIDENTS

Roger Anderson
John Armitstead
Daniel Ashby
Jannet Carmichael
Kevin Colgan
Debra Devereaux
Rebecca Finley
Diane Ginsburg
Harold Godwin
Mick Hunt
Marianne Ivey
Christene Jolowsky
Jill Martin Boone
Gerald Meyer²
Sara White
T. Mark Woods

STATE DELEGATES**Alabama (3)**

Charlie Cook
Thomas Cobb
Pamela Stamm

Alaska (2)

Traci Gale

Arizona (3)

Melinda Burnworth
Carol Rollins
Renee Tyree

Arkansas (2)

Rayanne Story
Lanita White

California (8)

Loriann DeMartini
Daniel Dong
Victoria Ferraresi
Steve Gray
Nancy Korman
Maria Serpa
Victoria Serrano-Adams
Steven Thompson

Colorado (3)

Michelle Hilaire

Karen McConnell

Michelle Then

Connecticut (3)

David Goffman
Molly Leber
Marta Stueve²

Delaware (2)

Michael Dejos

Florida (5)

Gary Dalin
Katelyn Dervay
Sandy Estrada
Charzetta James
Richard Montgomery

Georgia (3)

Leslie Jagers
Collin Lee
Jennifer Sterner-Allison

Idaho (2)

Paul Driver
Lindsay Hunt

Illinois (5)

Noelle Chapman
Travis Hunerdosse
Ann Jankiewicz
Jennifer Phillips
Carrie Sincak

Indiana (3)

Christopher Scott
Amy Sheehan
Tate Trujillo

Iowa (3)

Shane Madsen
Lisa Mascardo
Jamie Sinclair

Kansas (3)

Jeffrey Little
Joan Kramer
Lindsay Massey

Kentucky (3)

Scott Hayes
Vylinda Howard
Rachel Swope

Louisiana (3)

Jason Chou
Kisha Gant
Monica Morgan

Maine (2)

Matthew Christie
Chelsea Magee

Maryland (4)

Stacy Dalpoas
Janet Lee
Kristopher Rusinko
Kristin Watson

Massachusetts (4)

Caryn Belisle
Snehal Bhatt
Karl Gumpfer
Erin Taylor

Michigan (4)

David Bach
Jesse Hogue
James Lile
Michael Ruffing

Minnesota (4)

Melissa Carlson
Kevin Dillon
Paul Krogh
Brandon Ordway

Mississippi (2)

Joshua Fleming
Andrew Mays¹

Jameka Stuckey²

Missouri (3)

Laura Butkievich
Joel Hennenfent
Amy Sipe

Montana (2)

Lonnye Finneman
Jason Nickisch

Nebraska (2)

Michele Faulkner
Jerome Wohleb

Nevada (2)

Adam Porath
Katherine Ward

New Hampshire (2)

Jennifer Towle
Elizabeth Wade

New Jersey (3)

Luigi Brunetti
Paul Goebel
Julie Kalabalik

New Mexico (2)

Melanie Dodd
Devena Norris

New York (5)

Karen Berger
Leigh Briscoe-Dwyer
Anthony Longo
Elizabeth Shlom
Lisa Voigt

North Carolina (4)

Susan Bear
Robert Granko
Michael Melroy
Jacqueline Olin

North Dakota (2)

Lisa Richter

Ohio (5)

Amanda Hanson
Karen Kier
Scott Knoer
Katie McKinney
Chris Paxon

Oklahoma (3)

Ann Lloyd
Kari McCracken
Edna Patatanian

Oregon (3)

Michael Millard
Kathryn Norton
Daniel Rackham

Pennsylvania (5)

Lawrence Carey
Nishaminy Kasbekar
William O'Hara
Christine Roussel
Jean Schultz

Puerto Rico (2)

Yaritza Lopez

Rhode Island (2)

Shannon Baker
Karen Nolan

South Carolina (3)

Lynn Etheridge²
Natasha Nicol

South Dakota (2)

Jaclynn Chin
Rhonda Hammerquist

Tennessee (4)

Kelly Bobo
Jamie Chapman
Jodi Taylor
Casey White

Texas (6)

Tammy Cohen
Shane Greene
Katie Morneau
Sidney Phillips
Ryan Roux
Jeffrey Wagner

Utah (3)

Erin Fox
Elyse MacDonald
Krystal Moorman

Vermont (2)

Kevin Marvin
Renee Mosier

Virginia (4)

Scott Anderson
Lisa Hammond
Katelyn Hipwell
Natalie Nguyen

Washington, D.C. (2)

Carla Cabanilla Darling
Michelle Eby

Washington State (4)

Rena Gosser
Amanda Locke
Steven Riddle
Roger Woolf

West Virginia (2)

Jason Strow
Janet Wolcott

Wisconsin (4)

Terry Audley
David Hager
Justin Konkol
Lucas Schulz

Wyoming (2)

Linda Gore-Martin
Jamie Hornecker

SECTIONS AND FORUMS**DELEGATES****Ambulatory Care Practitioners**

Laura Traylor

Clinical Specialists and Scientists

Kimberly Benner

Inpatient Care Practitioners

Linda Spooner

Pharmacy Informatics and Technology

Joseph Lassiter

Pharmacy Practice Managers

Jennifer Tryon

New Practitioners Forum

John Hill

Pharmacy Student Forum

Judith Lovince

Pharmacy Technicians Forum

Barbara Hintzen

FRATERNAL DELEGATES**US Air Force**

Jin Kim

US Army

Christopher Ellison

US Navy

Jason Galka

US Public Health Svc

Jeffrey Gidlow

Veterans Affairs

Heather Ourth

¹Sat in Sunday House Meeting only

²Sat in Tuesday House Meeting only

House of Delegates

REPORT OF THE COMMITTEE ON NOMINATIONS

June 3, 2018

Denver, Colorado

John Pastor III (Chair), Minnesota
John Armitstead (Vice Chair), Florida
Kimberley Benner, Alabama
Steven Riddle, Washington
Meghan Swarthout, Maryland
David Weetman, Iowa
Lanita White, Arkansas
Noelle Chapman (1st Alternate), Illinois
Kethen So (2nd Alternate), California
Molly Leber (3rd Alternate), Connecticut

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.
- 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 5, 2017, at the Midyear Clinical Meeting in Orlando, Florida; and on April 19, 2018, at ASHP headquarters; and met once via teleconference. Review of nominees' materials was conducted continuously between March and April 2018 solely via secure electronic transmissions. This process has been reviewed for quality improvement and will be repeated for the 2018–2019 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 2017 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 650 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: 7 accepted

BOARD OF DIRECTORS: 23 accepted

CHAIR, HOUSE OF DELEGATES: 14 accepted

A list of candidates that were slated was provided to delegates following the Committee's meeting on April 19, 2018.

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

President-Elect

Kathleen S. Pawlicki, B.S.Pharm., M.S., R.Ph., FASHP (Southfield, MI)

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

Board of Directors

Kristina (Kristy) L. Butler, Pharm.D., B.S.Pharm., BCACP, FASHP, FOSHP (Portland, OR)

Nishaminy (Nish) Kasbekar, Pharm.D., B.S.Pharm., FASHP (Philadelphia, PA)

Pamela K. Phelps, Pharm.D., FASHP (Minneapolis, MN)

Jamie S. Sinclair, B.S.Pharm., M.S., FASHP (Cedar Rapids, IA)

Chair, House of Delegates

Melanie A. Dodd, Pharm.D., Ph.C., BCPS, FASHP (Albuquerque, NM)

Casey H. White, Pharm.D., M.B.A., BCCCP, BCNSP, BCPS, FASHP (Cookeville, TN)

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

CANDIDATES FOR PRESIDENT 2019–2020

KATHLEEN S. PAWLICKI, B.S.Pharm., M.S., R.Ph., FASHP (kathleen.pawlicki@beaumont.org) is Vice President and Chief Pharmacist at Beaumont Health in Michigan. After earning her B.S.Pharm. (Ferris State University), she completed an ASHP-accredited residency and an M.S. in Pharmacy Administration (Wayne State University [WSU]). Pawlicki has championed improved medication management by advancing pharmacist and technician roles at small, medium, and large hospitals. She values continual advocacy for regulatory issues surrounding pharmacy practice through leadership in state associations and as a member of the Michigan Board of Pharmacy.

Pawlicki's ASHP service includes Board of Directors; Chair, Section of Pharmacy Practice Managers; Council on Pharmacy Management; House of Delegates, Committee on Nominations; Task Force on Organizational Structure; and Chair, Task Force on Caring for Patients Served by Specialty Suppliers. In 2018 she was awarded the Michigan Pharmacist of the Year award. Previous accolades include the MSHP Joseph A. Oddis Leadership Award and WSU College Excellence in Teaching Award.

Statement:

As a profession, we have weathered various changes in healthcare and through hard work achieved a prominent place as the medication expert. As healthcare, technology, and society continue to evolve, we must remain diligent to further cement our future in caring for patients. Practice transformation, with a willingness to embrace new roles, leverage advanced technology, and navigate the unknown, will be critical to our success. The future world of healthcare will necessitate us to think and act differently. To be successful, we must:

- *Embrace new and evolving roles for both pharmacists and technicians, thinking beyond our current biases on how and where we practice.*
- *Leverage advanced technology, such as machine learning, predictive analytics, and automation, to transform highly manual processes into highly reliable automated systems and to allow for innovative approaches to clinical medication management.*
- *Support our teams' well-being through recognition and training on resiliency and effective work-life integration.*
- *Advocate for our role on the patient care team.*

It will be important for us to design our fate and how we effectively change our behaviors and mindset to embrace these new possibilities. I would be honored to focus my energy and creativity in leading ASHP into the future.

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. from the University of Iowa and completed an internal medicine residency at the Medical University of South Carolina. In his 28 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 (KSHP). 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 award. He has served as mentor to many pharmacy students and residents.

Statement:

The Oath of a Pharmacist states: "I vow to devote my professional life to the service of all humankind through the profession of pharmacy." We live this oath through our dedication to patients and through professional organization involvement. The role of professional organizations in this pursuit cannot be understated. ASHP has shaped me personally and professionally, and I am dedicated to the ongoing success of ASHP and its membership.

ASHP is a critical leader in the advancement of pharmacy. This is exhibited through multifaceted opportunities for members as well as in collaboration with external stakeholders. ASHP pursues excellence through advocacy, networking, and education, and serves as our collective voice in optimizing the impact of pharmacy on safe, effective, evidence-based, and affordable medication therapy. I am ready to lead ASHP in these pursuits.

I have been fortunate to serve ASHP in a number of capacities, including two terms as Treasurer. Being nominated to serve as your next President is a great honor. If elected, I would work fervently with the ASHP staff, Board, and membership to further advance health-system pharmacy. Together, we can live the virtues included in the Oath of a Pharmacist. Thank you for the opportunity to serve you.

CANDIDATES FOR BOARD OF DIRECTORS 2019–2022**KRISTINA (KRISTY) L. BUTLER, Pharm.D., B.S.Pharm., BCACP, FASHP, FOSHP**

(kristina.butler@providence.org) is the Manager of Clinical Pharmacy Specialists for Providence Medical Group Oregon Region. She earned her B.S.Pharm. and Pharm.D. from Oregon State University (OSU)/Oregon Health & Sciences University and completed a primary care residency through Providence Health & Services in Portland. Prior to her current position, Butler practiced as an ambulatory care clinical pharmacy specialist for 13 years.

Her service to ASHP includes Chair, Section of Ambulatory Care Practitioners; Chair, Council on Public Policy; Consensus Recommendations Panel Member, Ambulatory Care Conference & Summit; and delegate, House of Delegates. Butler has also held several leadership positions with the Oregon Society of Health-System Pharmacists (OSHP), including Annual Seminar Co-chair, Secretary, and President. She is a fellow of ASHP and OSHP, and a recipient of OSHP Pharmacist of the Year, OSHP Pharmacy Practitioner of the Year, and OSU College of Pharmacy's Outstanding Young Alumni Award.

Statement:

Ideal team-based care allows each expert to practice at top of scope, collaborating for a common goal: the patient's care. Pharmacists must position ourselves as key members of the healthcare team to ensure that every patient in every setting has access to the appropriate level of pharmacy services.

Similarly, as healthcare faces countless challenges — and opportunities — it requires highly functional teams of leaders who each contribute their expertise for a common goal: the quadruple aim. The pharmacy enterprise is uniquely qualified to lead and transform medication-use systems and continue to advance practice to meet the needs of our patients and the changing healthcare environment.

I believe that pharmacists must fully embrace our role as medication experts and leaders, and take accountability for all areas of medication use with individual patients and healthcare delivery as a whole. This belief is the foundation of my career as an ambulatory care clinician and administrator, and my service to the profession with ASHP. I am honored to be nominated for the Board of Directors and to have the opportunity to continue to passionately serve patients, pharmacy, and ASHP, and to advance the role of pharmacists and technicians in patient care and leadership teams.

NISHAMINY (NISH) KASBEKAR, Pharm.D., B.S.Pharm., FASHP (kasbeka@uphs.upenn.edu)

is Director of Pharmacy at Penn Presbyterian Medical Center in Philadelphia. Kasbekar earned her B.S.Pharm. and Pharm.D. from the Philadelphia College of Pharmacy and Science and completed residencies in pharmacy practice and infectious diseases at the Hospital of the University of Pennsylvania. She began her career providing direct patient care as an ID Clinical Specialist and as an administrator focused on creating entity and corporate inpatient and ambulatory patient-centered pharmacy services while also implementing a pharmacy residency program and automation for safe medication use.

Her ASHP service includes Chair, Section Advisory Group on Multi-Hospital Pharmacy Executives; Chair, Council on Pharmacy Practice; Women in Pharmacy Leadership Steering Committee; *AJHP* Editorial Board; and delegate to the ASHP House of Delegates for the last eight years. Additionally, previous leadership roles include Chair, Vizient Practice Advancement Committee; President, Pennsylvania Society of Health-System Pharmacists; and President, Pennsylvania Pharmacists Association Educational Foundation.

Statement:

As the healthcare landscape evolves, unique opportunities are being presented to our profession at a rapid pace. The increasing complexity of medications, rising drug costs, challenging regulations, and focus on outcomes have put pharmacists at the center of navigating initiatives that provide safe and quality care.

ASHP, my professional home, has been at the forefront in tackling these healthcare challenges and forecasting new roles that position our pharmacy leaders to prime our healthcare systems for sustained success.

As we look to the future, healthcare delivery will be significantly re-engineered, and the below focus areas will be important for ASHP:

- *Enabling members to create innovative strategic models for practice advancement*
- *Harvesting an entrepreneurial spirit such that optimal collaboration with disruptive innovators and vertical integrators will allow for leveraged partnerships*
- *Embracing technology to create new delivery models utilizing pharmacists outside of conventional ways*
- *Inspiring and leading the professional development of the younger workforce for effective succession planning*

As ASHP members, our unity of thought and continued pursuit of professional excellence will allow us to move forward strategically, creatively, and in a transformative way. I am honored by this nomination and would consider it a privilege to serve the profession.

PAMELA K. PHELPS, Pharm.D., FASHP (pphelps2@fairview.org) is System Director of Acute Care Clinical Pharmacy Services at Fairview Health Services in Minneapolis, Minn. She is Adjunct Associate Professor at the University of Minnesota College of Pharmacy. A University of Minnesota alumna, she began her career as a clinical pharmacy specialist in critical care. She is PGY1 Residency Program Director at the University of Minnesota Medical Center, having graduated 147 residents.

Phelps' service to ASHP includes Chair, Council on Therapeutics; ASHP Advisory Committee for the *Pharmacy Forecast*; chapter author for the *Pharmacy Forecast*; editor and author for ASHP's *Smart Infusion Pumps* book; ASHP Task Force on Accountable Care Organizations; Minnesota state delegate; and ASHP Council on Educational Affairs. She has served as a Chair and on the Executive Board for the Vizient (UHC) Pharmacy Council. Phelps has served in many state affiliate roles, including President and Board member of the Minnesota Society.

Statement:

For our profession to win, we must help pharmacists navigate the day-to-day frontline challenges, strategize for the future, and curate young practitioners to assume both big-L and small-l leadership roles. Winning as a residency director is seeing my residents go on to achieve wonderful things for our shared profession. It is giving presentations at national and local meetings and feeling as though I have created some sense of meaning and purpose. It is creating lifelong relationships forged by a love of the profession. And, it is using the gift of leadership and influence to advance the profession as a whole. We are facing unprecedented challenges, but every challenge, seen in a different light, brings opportunities for new victories.

Winning isn't an end game, however; it's a continuous process. As we consider what winning looks like for our profession, we must create bold policy strategies that drive the profession forward, support our membership in assuming new patient care roles, bolster our support for technician development and advancement, protect the public from exorbitant drug costs, become part of the opioid crisis solution, and ensure public access to pharmacists' care.

I would be honored to serve as an ASHP Board member.

JAMIE S. SINCLAIR, B.S.Pharm., M.S., FASHP (jsinclair@mercycare.org) is Director, Pharmacy Services for Mercy Medical Center, Cedar Rapids, Iowa. She earned her B.S.Pharm. from Massachusetts College of Pharmacy and her M.S. from the University of Minnesota, and she completed an ASHP-accredited residency at Methodist Hospitals of Memphis. Sinclair has practiced in academic and community-based settings, beginning as a critical care pharmacist, and for over 20 years she has held health-system leadership positions. She has dedicated her career to advancing pharmacy practice; implementing/optimizing technologies; leading medication safety initiatives; and developing students, residents, and pharmacist practitioners and leaders.

Sinclair has served ASHP in numerous capacities, including: Council on Pharmacy Practice; Chair, Commission on Affiliate Relations; Committee on Nominations; Women in Pharmacy Leadership Steering Committee; ASHP/ISMP Medication Safety Certificate Faculty; and state delegate. She is a member of the Iowa Pharmacy Association and past Treasurer and President of the Minnesota Society of Health-System Pharmacists.

Statement:

We, the health-system pharmacy profession, embody a patient-centric philosophy. If we prioritize this value, then our patient-specific, organizational, and professional goals will follow. And in doing so, we must:

- *Lead the adoption of new medication therapies and technologies while being agile when disruptors enter our area of expertise. We must lead the evaluation of new technologies and consider all disruptors potential opportunities to improve the well-being of the patients we serve.*
- *Continue our advocacy to improve transparency within the pharmaceutical industry. Medication costs and shortages can introduce unintended consequences when access to optimal medications is not available.*
- *Continue the pursuit of provider status. We must promote interprofessional relationships and invite other disciplines to advocate on our behalf for provider status.*
- *Ensure we prepare pharmacists for the increased level of accountability that will accompany the elevation of the profession with provider status.*

I consider this profession a privilege. I am grateful for my ASHP home and the people I have met; they have fulfilled me professionally and personally. I am humbled to be slated and would be honored to serve on the ASHP Board to further support and advocate for our patients and our profession.

CANDIDATES FOR CHAIR, HOUSE OF DELEGATES, 2018–2021

MELANIE A. DODD, Pharm.D., Ph.C., BCPS, FASHP (mdodd@salud.unm.edu) is Department Vice-Chair and Associate Professor, Department of Pharmacy Practice and Administrative Sciences, The University of New Mexico (UNM) College of Pharmacy. A Purdue University, UNM, and Presbyterian Healthcare Services residency program graduate, she began her career with the NM Medicaid DUR Program. She is now a pharmacist clinician with prescribing authority at the UNM Senior Health Clinic and a consultant hospice pharmacist. She is responsible for geriatric teaching activities with Pharm.D. and interprofessional students and residents. She has played an active role in development of new pharmacist clinical practice models, credentialing processes, and pharmacist reimbursement at UNM.

Dodd's ASHP service includes Chair and Vice-Chair, Council on Public Policy; Chair, Section of Ambulatory Care Practitioners; Pharmacy Practice Model Initiative delegate; and NM delegate to the House of Delegates. She is Past President of NMSHP and faculty advisor for the UNM SSHP.

Statement:

My vision is to have pharmacists providing direct patient care to all patients throughout the continuum of care as essential members of interprofessional teams. In addition, I believe it is important that we embrace and advocate for the expanding roles of pharmacists and support the ASHP Practice Advancement Initiative. Pharmacist recognition as providers is a core component to achieving this vision. Through ASHP's leadership, including the vision and efforts of the House of Delegates and our grassroots efforts, we can be successful in advancing healthcare. ASHP policy development is a core component of establishing and communicating our practice vision to our professional colleagues, our patients, and the community at large. Through my experiences as a pharmacist clinician, pharmacy educator, and administrator, and my service to SSHP, NMSHP, and ASHP, including chairing the Council on Public Policy and Section of Ambulatory Care Practitioners and being a delegate to the House of Delegates, I feel I am well positioned to chair the House of Delegates and represent the membership. I am humbled and honored by this nomination and committed to providing leadership to ASHP and the House of Delegates to continue to advance the practice of pharmacy and provide high-quality patient care.

CASEY H. WHITE, Pharm.D., M.B.A., BCCCP, BCNSP, BCPS, FASHP (CWhite@crmchealth.org) serves as Director of Pharmacy at Cookeville Regional Medical Center in Cookeville, Tenn. He earned his Pharm.D. from the University of Tennessee and his M.B.A. from the University of Memphis. White completed residency training at the Veterans Affairs Medical Center in Memphis. He is also a clinical instructor for the University of Tennessee, Lipscomb University, and Union University.

White has served in a number of capacities within ASHP, including the Council on Therapeutics; Chair, Section of Clinical Specialists and Scientists; and delegate to the House of Delegates for the past 10 years. He has also served as President of the Tennessee Society of Health-System Pharmacists (TSHP) and the Tennessee Pharmacists Association (TPA). White is a past recipient of the Pharmacist of the Year and Innovative Pharmacy Practice awards with TSHP and Young Pharmacist of the Year award with TPA.

Statement:

The ASHP House of Delegates (HOD) serves a vital role as a collaborative body gauging the needs and challenges of members, enacting professional policies to help guide the organization's priorities, and providing direction to advance the success of ASHP and its members. Only through embracing diverse

member perspectives can the HOD be successful in synthesizing actionable policies that shape our professional future.

As Chair, I will preserve the positive changes in HOD efficiency realized in recent years.

Additionally, I will focus on the following priorities:

- 1) Increasing transparency for the membership on actions that result from HOD recommendations*
- 2) Fostering improved communication strategies, including virtual opportunities to engage members and strengthen our efficiency and responsiveness*
- 3) Being a thoughtful and insightful leader who listens to all member viewpoints, facilitates consensus on important issues, and provides passionate representation on behalf of the HOD at the ASHP Board of Directors table*

Nomination for this position is an incredibly humbling honor. I have the utmost respect for the dignity and responsibility inherent in the chairmanship of the House of Delegates and will always strive to uphold it. I truly believe in the policy process, and I am grateful for the opportunity to serve.



House of Delegates

Board of Directors Report: Policy Recommendations for the June 2018 House of Delegates

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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.

Lea S. Eiland, *Board Liaison*

Council Members

Tricia Meyer, *Chair* (Texas)
Katherine Miller, *Vice Chair* (Illinois)
Nitish Bangalore (Wisconsin)
Erich Brechtelsbauer, *New Practitioner*
(Ohio)
Lynn Eschenbacher (Missouri)
W. Lynn Ethridge (South Carolina)
Kenneth Jozefczyk (Georgia)
Joanna Maki, *Student* (Minnesota)
Robert S. Oakley (Kentucky)
Richard Pacitti (Pennsylvania)
Victoria Serrano Adams (California)
Cynthia Williams (Virginia)
David Chen, *Secretary*

1. Medication Formulary System Management

- 1 To declare that decisions on the management of a medication formulary system,
- 2 including criteria for use, (1) should be based on clinical, ethical, legal, social,
- 3 philosophical, quality-of-life, safety, comparative effectiveness, and
- 4 pharmacoeconomic factors that result in optimal patient care; (2) must include the
- 5 active and direct involvement of physicians, pharmacists, and other appropriate
- 6 healthcare professionals; and (3) should not be based solely on economic factors.

(Note: This policy would supersede ASHP policy 0102.)

Rationale

A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and

cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

As described in more detail in the [ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System](#), a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the involvement of appropriate healthcare professionals, and are not based solely on economic factors.

Background

The Council reviewed ASHP policy 0102, Medication Formulary System Management, as part of ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Panel in making its recommendation discussed the importance of factoring comparative effectiveness considerations into the formulary decision process. It supports the premise that formulary decisions should not be made exclusively based on the cost of the medication. The Panel felt that comparative effectiveness is a different point of consideration than a pharmacoeconomic review. The Council voted to recommend amending policy 0102 as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; ~~and~~ (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; ~~further,~~

~~To declare that decisions on the management of a medication formulary system~~ and (3) should not be based solely on economic factors.

2. Manufacturer-sponsored Patient Assistance Programs

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

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

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

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

(Note: This policy would supersede ASHP policy 1420.)

Rationale

ASHP recognizes the value of patient assistance programs (PAPs) in improving continuity of care while controlling costs and advocates expanded use of these programs for uninsured and underinsured patients in ambulatory and inpatient care settings. Some organizations have demonstrated success in achieving the benefits of these programs through dedicated resources and a mastery of the many programs available. Simplification of these programs (similar eligibility criteria, a common data format) would reduce the resources required to participate and improve access and utilization. ASHP notes that while the number of PAPs in ambulatory care settings has increased, there has been little growth in programs for inpatients. Hospitals must then absorb the costs of patient care, which results in fewer resources in the overall healthcare system. ASHP believes that expansion of PAPs for high-cost drug products used for indigent inpatients would significantly offset some of the costs to hospitals and ultimately improve care. In addition, interprofessional cooperation will be needed to support patients in accessing drug products when the PAP doesn't cover the cost of the drug product due to high deductibles or co-pays. To ensure that these programs achieve their objectives, ASHP advocates that development of these programs ensure that they contain the elements of pharmacist patient care.

Background

The Council reviewed ASHP policy 1420, Manufacturer-sponsored Patient Assistance Programs, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Panel in making its recommendation suggested that PAPs should be available regardless of the source of the drug product (e.g., specialty pharmacy and limited distribution systems). The Panel also suggested that the rationale be amended to address instances in which the cost of the drug product is not entirely covered by the PAP due to high deductibles and co-pays. In addition, the Panel stated that pharmacists and pharmacy staff should facilitate patient access to PAPs; however, the Panel concluded that the focus of the policy should remain on advocating that manufacturers enhance access to PAPs. The Council voted to recommend amending policy 1420 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

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

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

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

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

3. Product Reimbursement and Pharmacist Compensation

- 1 To collaborate with public and private payers in developing improved methods of
- 2 reimbursing pharmacies for the costs of drug products dispensed, pharmacist services
- 3 (e.g., compounding, dispensing, drug product administration, patient monitoring, and
- 4 patient education), and associated overhead; further,
- 5 To educate pharmacists about those methods.

(Note: This policy would supersede ASHP policy 1304.)

Rationale

In well-intentioned efforts to reduce healthcare costs, public and private payers often seek to minimize the reimbursement to pharmacies for drug products. Historically, those reimbursements have sometimes exceeded the simple cost of the drug product to reimburse pharmacies for associated costs (e.g., storage, compounding, preparation, dispensing). Because cost-management efforts are likely to continue to reduce pharmacy reimbursement, other means of compensating pharmacies for those expenses will need to be found, and pharmacists will require education about those reimbursement methods. In addition, pharmacists and pharmacies need to be reimbursed for professional services associated with management of medications and related patient care.

Background

The Council reviewed ASHP policy 1304, Drug Product Reimbursement, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Panel in making its recommendation noted that there are new reimbursement mechanisms related to drug products that are not addressed in this policy. For example, reimbursement of administration and monitoring costs related to white bagging of medications, unused medications, 340B medications, and buy-and-bill programs. The Council

suggested a new title for the policy be considered, such as Product Reimbursement and Pharmacist Compensation, to capture the intent of the amendments that include cognitive and administration services. The Council voted to recommend amending policy 1304 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

~~To pursue, in collaboration with public and private payers, the development of improved methods of reimbursing pharmacies for the costs of drug products dispensed, compounding and dispensing services, and associated overhead; further,~~

To collaborate with public and private payers in developing improved methods of reimbursing pharmacies for the costs of drug products dispensed, pharmacist services (e.g., compounding, dispensing, drug product administration, patient monitoring, and patient education), and associated overhead; further,

To educate pharmacists about those methods.

4. Patient Access to Pharmacist Care Within Provider Networks

- 1 To advocate for laws that would require healthcare payers, when creating provider
- 2 networks, to include pharmacists and pharmacies providing patient care services within
- 3 their scope of practice when such services are covered benefits when delivered by other
- 4 healthcare providers; further,

- 5 To advocate for laws that would allow a pharmacy or pharmacist to participate as a
- 6 provider within a healthcare payer's network if the pharmacy or pharmacist meets the
- 7 payer's criteria for providing those healthcare services; further,

- 8 To acknowledge that healthcare payers may develop and use criteria to determine
- 9 provider access to its networks to ensure the quality and viability of healthcare services
- 10 provided; further,

- 11 To advocate that healthcare payers be required to disclose to pharmacists and
- 12 pharmacies applying to participate in a provider network the criteria used to include,
- 13 retain, or exclude pharmacists or pharmacies.

Rationale

As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacists working in those settings increasingly find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to

profitably operate), but when creating provider networks, payers should include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits when delivered by other healthcare providers. To ensure equal treatment for healthcare providers, payers should be required to disclose to those applying to participate in a provider network the criteria used to include, retain, or exclude providers. When pharmacists obtain provider status, the infrastructure required to implement direct, independent patient care and billing for provider-based services needs to be in place and be accessible. Ensuring pharmacists and pharmacies have the opportunity to engage and have access to payers and payer networks will improve patient access to pharmacists' care.

Background

The 2016 Council reviewed the issue of pharmacist and pharmacy access to payers. This issue was studied for two purposes: (1) as part of an assessment of provider status readiness, and (2) in response to a number of reports that hospital and health-system pharmacies were experiencing site-of-care and payer carve-outs. The 2016 Council proposed a new policy that focused on any willing provider statutes, that policy recommendation was debated by the House of Delegates in June 2016. Because the policy recommendation was the subject of debate and extensive amendment, the ASHP Board of Directors and the House of Delegates referred the policy recommendation and its amendments to the 2017 Council for further study.

In making its recommendation, the Board noted the importance and complexity of the subject matter, the substantial changes made to the recommendation on the floor of the House, the ability of ASHP staff to advocate on the topic based on existing policy, and the flexibility of the ASHP policy process to bring a revised and duly considered policy recommendation to the House in the near future. The Board commended the Council on taking action on a topic that will grow in importance as pharmacists gain more independence in practice on the path to provider status. The Board also recognized and appreciated the thoughtful deliberation that delegates engaged in to refine the policy recommendation from what was proposed to what resulted from amendment. The scope of the amendments indicated the legal and regulatory complexities of the topic, as well as the potential consequences of successful advocacy, and suggested that a longer period of due consideration would be beneficial. The Board observed that some organizations have had a long and difficult history in developing policy on this topic and concluded that the additional effort devoted to developing well-crafted and thoroughly vetted policy would be worthwhile.

Key elements that were suggested through the additional review on the topic included:

- Policy and advocacy for professionals' and healthcare organizations' access to or participation in payer networks is a critical issue for reimbursement and financial sustainability.
- Acknowledgement that payers need the ability to control access to their networks for financial sustainability, quality, and, in some cases, to help ensure a provider network can exist (e.g., if each provider doesn't have sufficient patient volume to operate there could end up being no providers in an area or region).
- It was advised that any willing provider laws should not be pursued specifically and to consider broader language as this gives more flexibility in advocacy and avoids the direct

controversy on application and potential negative implications of any willing provider laws.

- The American Medical Association and the American Pharmaceutical Association have similar policies advocating for fair and reasonable payer access.

The Council through its additional review decided to remove specific focus on any willing provider statutes and to recognize the balance needed on payer needs as well as pharmacist and pharmacy providers.

5. Health Insurance Policy Design

- 1 To advocate that all health insurance policies be designed and coverage decisions made in
- 2 a way that preserves the patient–practitioner relationship; further,
- 3 To advocate that health insurance payers and pharmacy benefit managers provide public
- 4 transparency regarding and accept accountability for coverage decisions and policies;
- 5 further,
- 6 To oppose provisions in health insurance policies that interfere with established drug
- 7 distribution and clinical services designed to ensure patient safety, quality, and continuity
- 8 of care; further,
- 9 To advocate for the inclusion of hospital and health-system outpatient and ambulatory
- 10 care services in health insurance coverage determinations for their patients.

(Note: This policy would supersede ASHP policy 1520.)

Rationale

Evolving practices by health insurers are negatively affecting patient care decisions and impacting the relationships between patients and their care providers. One common health insurance practice restricts management of and access to certain drugs to specialty suppliers. Another problematic practice is that certain drugs are not reimbursed by the insurer when used as part of the patient’s hospital or health-system care. Medicare, for example, deems certain drugs as self-administered drugs (SADs), which are not reimbursed when provided to a patient because they are not considered integral to the reason for admission. These practices increase the number of patients that “brown bag” medications when they are admitted to a hospital to avoid being charged personally for the uncovered medications. ASHP has identified a number of concerns about these practices, including impact on continuity of care, integrity of the drug supply, and impacts on patient satisfaction and public perception of healthcare organizations.

It is the responsibility of the pharmacist to ensure the integrity of drugs used in the care of patients in the healthcare facility in which he or she practices. Having to verify products that

patients bring with them from multiple suppliers disrupts the care process. Having patients go unreimbursed for a medication because it was administered in and supplied by the healthcare organization is confusing to the patient and damaging to the patient–provider relationship. More broadly, lack of understanding of the differing payment systems in different care settings leads to public relations challenges. In addition, the lack of transparency regarding how payers make certain coverage determinations and apply performance penalties (e.g., direct and indirect remuneration fees) creates a significant challenge for healthcare providers as they care for patients.

ASHP advocates reforming these insurance practices. Coverage of medications should not interfere with the safe and effective provision of care and should recognize the responsibility of pharmacists to ensure product integrity for care provided where they practice. In addition, ASHP advocates that the Centers for Medicare & Medicaid Services, commercial payers, and others include hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

Background

The Council voted to recommend amending ASHP policy 1520, Impact of Insurance Coverage Design on Patient Care Decision, as follows (underscore indicates new text):

To advocate that all health insurance policies be designed and coverage decisions made in a way that preserves the patient–practitioner relationship; further,

To advocate that health insurance payers and pharmacy benefit managers provide public transparency regarding and accept accountability for coverage decisions and policies; further,

To oppose provisions in health insurance policies that interfere with established drug distribution and clinical services designed to ensure patient safety, quality, and continuity of care; further,

To advocate for the inclusion of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

The Council discussed ASHP policies related to insurance design and payer access and contracting with the purpose of the answering questions which have arisen regarding the practices of pharmacy benefit managers (PBMs) and whether there should be more transparency for patient care providers, advocates, and payers relying on the PBMs to provide services or dictate contractual terms. The Centers for Medicare & Medicaid Services (CMS) has increasingly become concerned about the impact of PBMs on Part D patients and taxpayers. CMS has begun to [evaluate the impact](#) of PBM transparency on beneficiary cost-sharing, Medicare subsidy payments, and plan liability. Additional areas of concern about the lack of transparency of PBMs include (1) maximum allowable cost (MAC) pricing (the upper limit that a PBM or drug benefit plan will pay for generic drugs and multisource brands), (2) direct and

indirect remuneration fees, (3) inflated payments for generics, (4) pay-to-play contracts between PBMs and manufacturers, and (5) narrowing networks. The Council concluded that policy 1520, Impact of Insurance Coverage Design on Patient Care Decision, addressed the issues of insurance design but lacked a pointed statement on the need for transparency and recommended an amendment to the policy position.

6. Pharmacy Accreditations, Certifications, and Licenses

- 1 To advocate that healthcare accreditation, certification, and licensing organizations
- 2 include providers and patients in their accreditation and standards development
- 3 processes; further,

- 4 To advocate that healthcare accreditation, certification, and licensing organizations adopt
- 5 consistent standards for the medication-use process, based on established evidenced-
- 6 based principles of patient safety and quality of care; further,

- 7 To encourage hospitals and health systems to include pharmacy practice leaders in
- 8 decisions about seeking recognition by specific accreditation, certification, and licensing
- 9 organizations; further,

- 10 To advocate that health-system administrators, including compliance officers and risk
- 11 managers, allocate the resources required to support medication-use compliance and
- 12 regulatory demands.

(Note: This policy would supersede ASHP policy 1303.)

Rationale

Pharmacy leaders have years of experience managing the demands and challenges of ensuring that pharmacy services meet the standards of accreditation organizations. Until recently, this responsibility was predominantly achieved through accreditation by The Joint Commission (TJC) and compliance with state laws and Board of Pharmacy regulations, as well as with federal requirements (e.g., those of the Drug Enforcement Administration). Healthcare organizations with ambulatory care services (e.g., home infusion, specialty pharmacy, and durable medical equipment) have had to manage the additional accreditation process for these business units. Until recently, the number of accreditation standards pharmacy leaders needed to be knowledgeable about was limited. Three recent phenomena have increased this challenge for pharmacy leaders: (1) TJC is no longer the only accreditor for hospitals and health systems; (2) healthcare organizations are developing or acquiring new business units that have their own accreditation processes that need to be integrated into existing ones; and (3) new accreditation, certification, or licensure processes have been created for services and businesses pharmacy leaders are responsible for.

The expansion of healthcare organizations and the growth of the pharmacy enterprise are creating a new environment with multiple accreditors and regulators, creating the challenge of compliance with overlapping accreditation, certification, and regulatory standards. Examples include the Michigan Board of Pharmacy requirement to obtain certification to conduct compounding and the California Board of Pharmacy requirement that each IV hood must have its own pharmacy license. In addition, community pharmacy accreditation processes and standards are being implemented that pharmacy leaders need to consider as well.

ASHP recognizes the difference between certifications that are the sole responsibility of and have a direct impact on a pharmacy and certifications of a healthcare organization's service line (e.g., stroke or transplant services) that are the responsibility of the organization but have medication management components that need to be addressed by the pharmacy. Pharmacists and pharmacy departments are being challenged by a growing number of required accreditations, certifications, and licensures, which result in increased need for pharmacist-in-charge designations, workforce fatigue, and direct and indirect costs.

Background

The Council voted to recommend amending ASHP policy 1303, Proliferation of Accreditation Organizations, as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,

To advocate that ~~encourage~~ healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidenced-based principles of patient safety and quality of care; further,

To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,

To advocate that health-system administrators, including compliance officers and risk managers, allocate the resources required to support medication-use compliance and regulatory demands.

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.)

- Interoperability of Patient Care Technologies (1302)
- Clinical Decision Support Programs (1212)
- Technician-Checking-Technician Programs (0310)
- ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Regulatory Impact on Shared Services Development

The Council discussed shared services for multi-hospital organizations, and although not a new phenomenon, with the rapid growth of mergers and acquisitions over the past 10 years healthcare executives are more aggressively seeking ways to optimize efficiencies and increase standardization across these large enterprises. In tandem with this organizational focus, pharmacy executives are also leveraging shared services for their various models of owned, affiliated, and contracted multi-hospital systems. Moreover, this organizational focus brings the decision making to the forefront on what services will be the most effective and efficient as shared services as well as the associated compliance and regulatory requirements..

The Council recommended that ASHP create resources that provide guidance on areas including TPN management, automation fulfillment, centralized order verification, automated dispensing cabinet, order verification for non-24-hour sites, telehealth, community pharmacy services, supply chain storage, and centralized fill of clinics. The Council suggested a survey of multi-hospital health systems would be useful to determine the scope of shared services in the marketplace including lessons learned on licensures and certifications being acquired. It was also suggested ASHP evaluate state rules and laws that impact shared services (e.g., when one state licenses a central Rx as wholesaler and another as a pharmacy).

Role of Pharmacy Services in Micro-Hospitals

The Council discussed the development of micro-hospitals that are emerging across the United States, especially in the Western states, to fill gaps in care for both underserved and Medicaid patients in addition to well-insured patients. Micro-hospitals can be considered a middle ground between full-scale hospitals and ambulatory care, free-standing emergency departments, and urgent care sites. They are open 24/7, have 8-10 inpatient beds, and range in size from about 15,000 to 50,000 square feet. These micro-hospitals are best positioned to service low-acuity illnesses, and it is ideal that they are within 20 miles of a full-service hospital in case a higher level of care is warranted. In general, patients are not expected to stay greater than 48 hours, and if longer care is required, then transfer to a full-service hospital is likely needed.

The Council recommended that ASHP provide education for members on micro-hospitals and how state rules and accreditation and payer differences will interplay, including information around the emerging trends of care locations (e.g., micro-hospitals, free-standing EDs, surgical centers). The Council decided this should be a topic for further discussion during its winter conference call.

Pharmacist Role in Medication-Related Electronic Health Record (EHR) and Technology Build and Maintenance

The Council discussed the increasing complexity and adoption of electronic health records and technologies that rely on medication information or medication-related data and how it has become increasingly important to treat the building and maintaining of medication-related files, clinical decision support, and interfaces with the same level of accountability as direct patient care performed by healthcare professionals.

The Council noted that even though there are now many pharmacists trained in informatics and more than willing to complete the work, some healthcare organizations continue to outsource tasks to the EHR vendor or other outside parties. Healthcare organizations and pharmacy departments are fighting to be allowed to have hands-on involvement, often unsuccessfully, to the point where it has developed into a safety issue.

The Council reviewed ASHP's related policies and statements in responding to the House of Delegates recommendation to address the need for more specific policy addressing the need to incorporate pharmacists in leadership roles in providing oversight and accountability for

these medication-related technology and EHR activities. The Council agreed a more strongly worded policy to address the issues and patient safety concerns is needed. The Council, in collaboration with the Section of Pharmacy Informatics and Technology's Chair, decided these policies and statements need to be reviewed in aggregate and the Section will provide proposed language as needed.

Patient Stratification and Managing Pharmacist Workload for Optimal Outcomes and Value

The Council reviewed four purposes of patient stratification in managing the pharmacy: external benchmarking (i.e., comparison with pharmacies from other organizations); deployment of pharmacy resources; frontline staff patient prioritization tools; and internal benchmarking and performance metrics (e.g., for meeting pharmacy and organizational expectations, demonstrating value to organizational leadership, or avoiding cost and generating revenue).

The Council's discussion resulted in the following recommendations:

- Investigate the opportunity to develop best practices around clinical decision support, formulas, and tools for patient stratification for pharmacy purposes
- Consider amending ASHP policy position 1212, Clinical Decision Support Systems, to address methods for validating CDS data and metrics for continuous quality improvement, after verifying whether current ASHP statements or guidelines address the issues.
- Encourage additional research on outcomes and benchmarking with patient stratification and clinical work by pharmacists.

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.

Todd A. Karpinski, *Board Liaison*

Council Members

Lisa Mascardo, *Chair* (Iowa)
Joseph Slechta, *Vice Chair* (Kansas)
Charles Berds, *New Practitioner*
(Massachusetts)
Jason Bergsbaken (Wisconsin)
Brooke Blay, *Student* (Ohio)
Jennifer Burnette (Texas)
Noelle Chapman (Illinois)
Mark Dunnenberger (Illinois)
Donald Filibeck (Ohio)
Michael Ganio (Ohio)
Jason Hutchens (Tennessee)
LeeAnn Miller (Connecticut)
Deborah Pasko, *Secretary*

1. Use of International System of Units for Patient-related Measurements

- 1 To advocate that the U.S. healthcare system adopt and only use the International System
- 2 of Units (SI units) for all patient-related measurements and calculations; further,

- 3 To advocate that healthcare organizations use clinical decision support systems and
- 4 equipment that allow input and display of patient-related measurements and calculations
- 5 in SI format only; further,

- 6 To promote education in the use of SI units and the importance of using SI units to
- 7 prevent medical errors.

Rationale

National healthcare, quality, and safety organizations have for years promoted the sole use of SI units for dosing and weight measurements. Errors in conversion from pounds to kilograms have caused two-fold overdosing and significant underdosing, particularly among pediatric patients, where even small dosing changes can have profound effects. Conversion to and from English units of volume (e.g., from milliliters to teaspoons) has long been identified as a source of dosing errors. These types of errors have been reported in all phases of the medication-use process (e.g., prescribing, preparation, dispensing, and administration) in all patient care settings.

Official labeling for U.S. drug products provides weight-based dosing only in SI units (e.g., mg/kg), so use of any other units introduces a risk of error. ASHP endorses national and institutional efforts to standardize the measurement and communication of patient weight using only SI units (i.e., grams and kilograms) but recognizes that other patient measures are sometimes used in dosing and other health-related calculations (e.g., body surface area, creatinine clearance, glomerular filtration rate, body mass index, or adjusted body weight). ASHP therefore advocates sole use of SI units by healthcare providers during prescribing, preparation, dispensing, and administration of medications in all patient care settings. To promote that practice, clinical decision support systems (e.g., electronic health record) and equipment (e.g., scales, stadiometers, infusion pumps) be structured to allow input and display of patient-related measurements and calculations in SI format only. Finally, education in how to use SI units, and about the importance of using SI units to prevent medical errors, will be required to overcome cultural resistance by healthcare providers, caregivers, and patients regarding SI unit use.

Background

The Council considered this topic as a companion to recently adopted ASHP policy 1721, Clinical Significance of Accurate and Timely Height and Weight Measurements, which endorses interprofessional efforts to ensure that accurate and timely patient height and weight measurements are recorded in the patient medical record. The Council concluded that advocating the sole use of SI units for weight measurements would promote the accuracy of weight measurement but recognized that adoption of that practice for other measures used in patient care would further the goal of reducing medical errors.

2. Availability and Use of Appropriate Vial Sizes

- 1 To advocate that pharmaceutical manufacturers provide drug products in vial sizes that
- 2 reduce pharmaceutical waste (e.g., multiple-dose vials or single-dose vials of differing
- 3 doses); further,

- 4 To collaborate with regulators, manufacturers, and other healthcare providers to develop
- 5 best practices on the appropriate use of single-dose, single-use, and multiple-dose vials.

Rationale

A [2016 study](#) estimated that the U.S. may spend close to \$2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Since that landmark study, policymakers, healthcare providers, and payers have been calling for action on vial sizes. The Centers for Medicare & Medicaid Services (CMS) has begun to require that billing for Part B drug products distinguish between claims for those received by a patient and those for [discarded](#) drug product, and the Office of the Inspector General (OIG) of the Department of Health and Human Services has initiated a study to determine the cost of such waste. Considerable savings could be gained if vial sizes

more closely matched doses, and one of the goals of the OIG study is to determine how much could be saved by using vial sizes available overseas that more closely match doses. As [one analysis](#) has pointed out, pharmacoeconomic analyses done in the U.S. typically do not incorporate leftover drug product in cost calculations, which may inflate cost-effectiveness ratios, and drug manufacturers may be exploiting that omission. In contrast, the United Kingdom National Institute for Clinical Excellence [requires](#) manufacturers to include the cost of leftover drug in manufacturers' submissions, and vials of two cancer drugs studied (bortezomib and pembrolizumab) contain 1 mg and 50 mg, respectively, in the U.K., and 3.5 mg and 100 mg in the U.S.

ASHP advocates that pharmaceutical manufacturers provide drug products in vial sizes that reduce drug waste (e.g., multiple-dose vials or single-dose vials of differing doses), and that regulators, manufacturers, and healthcare providers cooperate to develop and implement best practices for drug vial optimization.

Background

The Council considered this topic in response to a recommendation from the House of Delegates. As high drug costs and drug shortages continue to plague healthcare settings, there is heightened attention to the need for pharmaceutical companies to package products in containers, most typically vials, that more closely match the dose the patient may receive so there is less waste. Pharmacy budgets continue to draw scrutiny, and decreasing waste from single-dose vials would help alleviate costs while still serving patient needs. In addition, capturing the remaining product from vials is one method of addressing drug shortages.

Pharmacy departments have tried to institute operational changes to address the waste from vials, but these strategies often cannot be applied and the unused portion of drug in the vial is simply thrown away. One strategy that pharmacies employ is the use of a one-way dispensing spike that allows multiple doses to be drawn from only one vial puncture. This process is more often used by large pediatric institutions, in which vial sizes are often considerably disproportionate to patient doses. However, not all vials are conducive to using this method (e.g., when the surface area of the rubber stopper of the vial is too small).

3. Use of Closed-System Transfer Devices to Reduce Drug Waste

- 1 To recognize that peer-reviewed evidence supports the ability of specific closed-system
- 2 transfer devices (CSTDs) to maintain sterility beyond the in-use time currently
- 3 recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used
- 4 with aseptic technique and following current sterile compounding standards; further,

- 5 To foster research on standards and best practices for use of CSTDs for drug vial
- 6 optimization; further,

- 7 To educate healthcare professionals, especially pharmacists and pharmacy technicians,
- 8 about standards and best practices for use of CSTDs in drug vial optimization.

Rationale

A 2016 study estimated that the U.S. may spend close to \$2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Considerable savings are gained when the leftover contents of those vials are used. One practice that has shown promise in optimizing use of leftover drug product is the use of closed-system transfer devices (CSTDs) to facilitate the transfer of drug product from one reservoir to another. CSTDs provide a mechanical barrier that prevents the release of hazardous drugs and so have primarily been used throughout the medication-use process to minimize healthcare workers' exposure to hazardous drugs. CSTDs' mechanical barriers also prevent the ingress of environmental contaminants, however, which has prompted study of their ability to prolong the sterility and stability of drug product in vials. A growing number of studies have been generating data that indicate specific CSTDs have the possibility of maintaining sterility and extending in-use time when used under sterile conditions defined by United States Pharmacopeia Chapter 797. Although many of the approved CSTDs have an indication for use to prevent microbial ingress, with studied dwell times of up to 168 hours when maintained in an ISO Class 5 environment using proper aseptic technique, they do not have an explicit indication for extending the in-use time of drug products. Until the data from the studies can be validated and applied, standard-setting entities and regulators will not permit this practice. ASHP therefore advocates that the peer-reviewed evidence that supports the ability of properly used CSTDs to maintain sterility and extend in-use times be recognized, and that development of best practices for using CSTDs for drug vial optimization be encouraged.

Background

The Council considered this topic in response to a recommendation from the House of Delegates. In 2004, the National Institute of Occupational Safety and Health (NIOSH) defined a CSTD as a "drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system." Therefore, a CSTD is a medical device that has the potential to serve two important roles in medication preparation and administration. The first is to minimize healthcare worker and patient exposure to hazardous medications. For those institutions that handle hazardous medications, use of CSTDs is increasing and will eventually become an expectation. Currently, USP General Chapters 797 and 800 recommend that hospitals and health systems that prepare and administer hazardous medications should provide access to CSTDs. Second, with its potential to prevent ingress of microbes from the environment, CSTDs may serve to preserve the sterility of a medication in a single dose vial after puncture, rendering it sterile past the current 6-hour in-use time. The latter is an important consideration for institutions that seek to maximize the amount of drug available to be utilized through the extension of sterility of medication vial content. In fact, based on information from BD, the PhaSeal product information sheet estimates that "24% of hospitals that employ CSTDs use them to extend the dating of products as part of drug vial optimization programs."

Discussion among Council members demonstrated concurrence that CSTD use is already a standard for minimizing exposure to hazardous drugs and that it could become a standard for

maximizing drug vial optimization as well. Council members discussed the need for further study of these practices and for greater awareness among healthcare workers on proper handling and use of CSTDs but, in the meantime, urged immediate uptake for maximizing healthcare worker safety and careful evaluation for use in minimizing medication waste.

4. Collaborative Drug Therapy Management

1 To discontinue ASHP policy 9801, which reads:

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

6 To recognize that pharmacists participate in collaborative drug therapy management
7 for a patient who has a confirmed diagnosis by an authorized prescriber; further,

8 To recognize that the activities of a pharmacist in collaborative drug therapy
9 management may include, but not be limited to, initiating, modifying, and monitoring
10 a patient's drug therapy; ordering and performing laboratory and related tests;
11 assessing patient response to therapy; counseling and educating a patient on
12 medications; and administering medications.

Background

The Council discussed ASHP policy 9801 as part of sunset review. The Council determined that the policy is redundant with ASHP policies 1715, Collaborative Practice; 1005, Medication Therapy Management; and 0905, Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Drug Therapy Management, and is no longer needed.

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.)

- Code of Ethics for Pharmacists (9607)
- Medication Administration By Pharmacists (9820)
- Expression of Therapeutic Purpose of Prescribing (0305)
- Pharmacist Support for Dying Patients (0307)
- Education About Performing-Enhancing Substances (1305)
- Standardization of Intravenous Drug Concentrations (1306)

Other Council Activity

Guidance for Compounding Sterile Preparations in Short Supply

The Council considered a recommendation from the House of Delegates that ASHP develop guidance for healthcare systems for compounding sterile products that are in short supply or on backorder due to national shortages. The recommenders noted that healthcare systems across the U.S. are experiencing shortages of emergent medications and suggested that having guidance would ensure that healthcare facilities are acting in uniformity and with accurate scientific data for compounding these medications. The Council noted that ASHP has extensive policy regarding drug shortages and that the recommenders were seeking a how-to, tactical guide. Several Council members agreed to author an article for AJHP related to practical, operational experiences in addition to creating an informational document outlining algorithmic decision-making and tactics to use during drug shortages.

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff

representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Support for Stewardship Programs

The Council considered a recommendation from the House of Delegates that ASHP consider developing policy to advocate for dedicated pharmacy workforce to meet the needs of antimicrobial stewardship programs, including adequate support for the pharmacist time and related resources required to develop, implement, and sustain antimicrobial stewardship programs. The recommenders also suggested ASHP policy might be needed to address global stewardship issues, as other areas such as pain stewardship and other topics may arise. The Council acknowledged that there is new pressure on hospitals and health systems to develop, implement, and sustain stewardship programs, particularly antimicrobial stewardship programs, given the 2017 Joint Commission standards. Further, the Council shares the recommenders' concern that the healthcare community may be asked to develop stewardship programs for other topics in the future.

The Council concluded that current ASHP policy, particularly the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control and the ASHP Statement on the Health-System Pharmacist's Role in National Health Care Quality Initiatives, adequately addresses the immediate need for ASHP policy on 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.

Timothy R. Brown, *Board Liaison*

Council Members

Pamela Stamm, *Chair* (Georgia)
Chris Fortier, *Vice Chair* (Massachusetts)
Mary Durham, *New Practitioner* (North Carolina)
Ewa Dzwierzynski (Rhode Island)
Erin Fox (Utah)
Roy Guharoy (Missouri)
Mark Hamm (Ohio)
Janet Lee (Maryland)
Jeff Little (Kansas)
Meredith Oliver, *Student* (Mississippi)
Melissa A. Ortega (Massachusetts)
Michael Powell (Nebraska)
Joseph M. Hill, *Secretary*

1. ASHP Statement on Advocacy as a Professional Obligation

- ¹ To approve the ASHP Statement on Advocacy as a Professional Obligation (Appendix A).

Background

This statement was originally suggested by the PAC/Grassroots Advisory Committee and was also a recommendation from the House of Delegates at the 2017 Summer Meetings. The Council discussed the statement and agreed that advocacy is a professional responsibility. The Council agreed that other health professions have developed similar statements on advocacy and that ASHP should do so as well. Further, the Council voted to recommend approval of the language as written. However, the Council also debated whether the statement should define advocacy and agreed that providing a definition was suitable, although the Council felt it to be more appropriate to put in the background rather than the statement.

The Council further recommended an *AJHP* article, op-ed, or themed issue on advocating for patients and better patient care. The *AJHP* issue could include the statement on advocacy as a professional responsibility but would be expanded to go above advocating for the profession to include advocating for patients as well. The Council noted that this statement is also in line with Goal 5 of the ASHP strategic plan. Finally, the Council suggested that all or a portion of the statement be listed within the advocacy portion of the ASHP website.

2. Direct and Indirect Remuneration Fees

- 1 To advocate that private payers be prohibited from recovering direct and indirect
- 2 remuneration fees from pharmacies on adjudicated claims; further,
- 3 To oppose the application of plan-level quality measures on specific providers, such as
- 4 participating pharmacies.

Rationale

Direct and indirect remuneration (DIR) fees are a growing concern among pharmacies that dispense medications in a retail pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for the Centers for Medicare & Medicaid Services (CMS) to account for the true cost of the drug dispensed, including manufacturer rebates and pharmacy concessions. Often these rebates and concessions were unknown until the drug was dispensed and the claim adjudicated. Recently, a concerning trend has emerged in which pharmacy benefit managers (PBMs) charge DIR fees to pharmacy providers, applying their own plan performance measures as a way to assess fees on pharmacies dispensing covered Part D drugs. These fees are problematic for the following reasons:

- The fees are arbitrary and appear to result from an unintended application of measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied tend to be based on maintenance medications such as blood pressure or medications used to treat diabetes. These measures were never intended to be applied to specialty medications, or other specialized disease states such as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.
- PBMs are not required to define, justify, or explain to providers or to CMS the rationale or process for imposing their DIR fees.

Pharmacies providing specialty medications have been especially hard hit by DIR fees, due to the fee structure. DIR fees can be a flat rate (a fixed amount per dollar per claim) or a percentage (typically 3-9%) of the total reimbursement per claim. When the percentage-based structure is applied, the fees increase markedly for specialty drugs, which are typically much more expensive than maintenance medications.

Even more disturbing is that the fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment. Questions also remain as to whether Part D plan sponsors have the authority to assess DIR fees on pharmacies. There are no references to DIR fees collected on pharmacies in either the Medicare Modernization Act or corresponding CMS regulations.

DIR fees have led to higher cost-sharing responsibilities for Medicare beneficiaries, causing more of them to enter the Part D “donut hole” in which they are solely responsible for the cost of a drug. Because of higher costs, adherence rates tend to be lower among beneficiaries in the donut hole. These higher costs are a perverse result contrary to the very

reason DIR fees were created – passing savings onto beneficiaries.

Pharmacies are not alone in their concern. In January 2017, CMS published a [fact sheet](#) expressing concern over DIR fees and cited them as contributing to increased drug costs, beneficiary out-of-pocket spending, and Medicare spending overall. ASHP supports legislation that would address the problem of DIR fees. For example, H.R. 1038/S. 413, the [Improving Transparency and Accuracy in Medicare Part D Drug Spending Act](#), would prohibit Medicare Part D plan sponsors from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D.

Background

In the spring of 2017, ASHP developed an issue brief that outlined concerns and made a recommendation that ASHP advocate to prohibit or limit DIR fees. The issue brief and plan of action were approved by the Board of Directors at its April 2017 meeting. At the 2017 Summer Meetings, a member of the House of Delegates made a recommendation for the Council on Public Policy to develop policy on DIR fees. The Council added this to its agenda but also discussed on the July 2017 conference call whether the policy should be expanded to include pharmacy benefit management (PBM) transparency as a whole. It was noted that the Council on Pharmacy Management is exploring policy on PBM transparency and that the DIR issue is focused specifically on pharmacy reimbursement rather than the larger issue of transparency. Therefore, the Council felt that policy specifically around DIR fees should be developed, and that the larger issue of PBM transparency should proceed in the Council on Pharmacy Management. The Council also factored the decision by the ASHP Board to proceed with advocacy around the DIR issue to warrant the need for DIR-specific policy. As originally drafted, the new policy language focused on the Medicare Part D program; however, the Council did note that the issue could be about more than Part D drugs. The final recommendation was to get rid of the part D reference and not limit the policy to PBMs, thus keeping the policy broad.

3. Impact of Drug Litigation Ads on Patient Care

- 1 To oppose drug litigation advertisements that could lead patients to modify or
- 2 discontinue therapy without consulting their providers; further,

- 3 To advocate that drug litigation advertisements that may cause patients to discontinue
- 4 medically necessary drugs be required to provide a clear and conspicuous warning that
- 5 patients should not discontinue drugs without seeking the advice of their healthcare
- 6 provider.

Rationale

Many law firms use advertising as a means to generate clients for future litigation, including litigation regarding drugs. These advertisements can generate unnecessary fear for patients taking those drugs and may lead them to discontinue medically necessary therapies. Abruptly discontinuing a drug without consulting a healthcare provider can lead to failed therapy and

other adverse effects (e.g., some drugs require a tapered withdrawal to be safely discontinued, and patients on multiple medications may require new dosing or drug interaction assessments). Other than truth-in-advertising laws, there is currently no oversight of these advertisements and no requirement to warn patients about the potential harmful effects of discontinuing their drugs. ASHP agrees with the [American Medical Association](#) that such ads should be required to have clear and conspicuous warnings that direct patients to speak with their healthcare providers before discontinuing any drug.

Background

This policy recommendation was made at the 2017 Summer Meetings from the House of Delegates. The initial recommendation was to ban 1-800-Bad-Drug ads. The Council discussed this potential new policy and decided that it would not be appropriate to develop policy advocating for an outright ban on the ads. The Council was concerned that such a ban would not survive a constitutional legal challenge that it would impede the right to free speech. Instead, the Council drafted new policy language that opposes the ads unless a certain condition is met. The condition is that the ads must include conspicuous notification urging patients not to discontinue therapy without first talking to their provider. The Council voted to recommend the policy language above as new ASHP policy.

4. Approval of Biosimilar Medications

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

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

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

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

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

- 12 To oppose any state legislation that would require a pharmacist to notify a prescriber
- 13 when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

- 14 To support the development of FDA guidance documents on biosimilar use, with input
- 15 from healthcare practitioners; further,

- 16 To require postmarketing surveillance for all biosimilar medications to ensure their
- 17 continued safety, effectiveness, purity, quality, identity, and strength; further,
- 18 To advocate for adequate reimbursement for biosimilar medications that are approved by
- 19 the FDA; further,
- 20 To promote and develop ASHP-directed education of pharmacists about biosimilar
- 21 medications and their appropriate use within hospitals and health systems; further,
- 22 To advocate and encourage pharmacist evaluation and the application of the formulary
- 23 system before biosimilar medications are used in hospitals and health systems.

(Note: This policy would supersede ASHP policy 1509.)

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. The FDA approved its first biosimilar application in March 2015 for filgrastim-sndz, and others (e.g., adalimumab-adbm, adalimumab-atto, bevacizumab-awwb, etanercept-szsz, infliximab-abda, infliximab-dyyb) have followed.

At the state level, legislation has been proposed and enacted requiring patient and/or prescriber notification that a biosimilar medication has been interchanged. It is important to note that pharmacists cannot substitute a biosimilar medication unless the FDA has deemed that biosimilar to be interchangeable. As of 2017, 35 States and Puerto Rico have passed biosimilar substitution laws.

In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, Georgia's biosimilar law requires the pharmacist to notify the prescriber within 48 hours of dispensing the medication (excluding weekends and holidays).

ASHP supports legislation and regulation that would authorize the FDA to determine the interchangeability of biosimilars, thus permitting the substitution of biosimilars for the reference product without the intervention of the prescriber. Further, ASHP opposes the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance and opposes any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed. FDA's determination of interchangeability should be all that is needed in order to substitute the biosimilar with the reference product. Although FDA guidances are distinct from FDA regulations, they often have profound impacts on healthcare decisions and delivery, so ASHP encourages the FDA to include healthcare practitioners in their development.

ASHP recognizes that postmarketing surveillance and pharmacist evaluation as part of the formulary system before biosimilar use are required to guarantee safe use of biosimilar medications. ASHP also advocates for adequate reimbursement for biosimilars approved by the FDA.

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to amend ASHP policy 1509, Approval of Biosimilar Medications, as follows (underline indicates new text; ~~striketrough~~ indicates deleted text):

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

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

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

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

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

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; further,

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

To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA ~~deemed interchangeable~~; further,

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

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

In making its recommendation, the Advisory Panel discussed several considerations and perspectives related to this policy and biosimilars overall. Biosimilars represent a seismic shift in the medication use and care delivery process; pharmacists must be prepared to lead on any

regulatory, reimbursement, or patient care activity related to them. Also, the pace in which policies and practice changes are being considered related to biosimilars demands that this policy be reviewed and updated frequently in order to adequately capture current knowledge base and trends in the market. The addition of language related to FDA guidances, current and anticipated, was added because the policy was currently silent on the topic. While FDA guidances are distinct from FDA regulations, they have and will have a profound impact on health care decisions and delivery. The Panel also felt that there needs to be adequate reimbursement for all biosimilar medications that are submitted and approved through 510(a) and 510(k) pathways, independent of whether that biosimilar is deemed interchangeable.

5. 340B Drug Pricing Program Sustainability

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

- 4 To advocate legislation or regulation that would optimize access to the 340B program in
- 5 accordance with the intent of the program; further,

- 6 To advocate with state Medicaid programs to ensure that reimbursement policies
- 7 promote 340B program stability; further,

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

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

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

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

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

(Note: This policy would supersede ASHP policy 1407.)

Rationale

Statutory and other policy changes to the federal drug pricing (“340B”) program in recent years have spurred an increase in the number of hospitals and other eligible entities that participate. Since the program’s inception, the number of 340B-eligible and participating hospitals has continued to grow. Policymakers and other stakeholders have raised questions about the integrity of the program as well as its original intent. In addition, compliance with the current program continues to be challenging. Specifically, clarification to existing policy guidance or via newly proposed regulation is needed with respect to various issues. These include the definition of a patient, use of contract pharmacies, eligibility by various hospitals, and use of group purchasing organizations to purchase drugs for inpatient and outpatient use. Moreover, expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) allowed additional hospitals to participate in the program, further driving scrutiny and questions from policymakers and stakeholders. In response to policymaker and stakeholder concerns, ASHP recognizes the important intent and role of the 340B program and stresses the need for its continued sustainability. These developments demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment.

The original intent of the 340B program was to “to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (H.R. Rept. 102-384, pt. 2, at 12 [1992]). ASHP believes that the program should expand in alignment with its intent, which may or may not include use in the inpatient setting. ASHP emphasizes the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. Further, there is a need for communication and collaboration with state Medicaid programs to ensure optimization of benefits from the 340B program and Medicaid reimbursement policies. Because manufacturers must offer 340B discounts to covered entities to have their drugs covered by Medicaid, Medicaid policies will impact organizations with a 340B program. These impacts include but aren’t limited to disproportionate share adjustment percentages, outpatient drug reimbursement policies, and drug rebate programs (i.e., whether a covered entity is “carved in” or “carved out”).

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel’s recommendation to recommend amending ASHP policy 1407, 340B Drug Pricing Program Sustainability, as follows (underline indicates new text):

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

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate with state Medicaid programs to ensure that reimbursement policies promote 340B program stability; further,

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

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

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

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

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

In making its recommendation, the Advisory Panel discussed the need for communication and collaboration with state Medicaid programs in order to ensure equal benefit exists with 340B covered entities and Medicaid reimbursement policies. Given that manufacturers must offer 340B discounts to covered entities to have their drugs covered by Medicaid, Medicaid policies will impact organizations with a 340B program. This includes but isn't limited to disproportionate share adjustment percentages, outpatient drug reimbursement policies, and drug rebate programs (i.e., whether a covered entity is "carved in" or "carved out").

6. Federal Review of Anticompetitive Practices and Price Increases by Drug Product Manufacturers

- 1 To strongly oppose anticompetitive practices by drug product manufacturers that adversely affect drug product availability and price; further,
- 2
- 3 To encourage appropriate federal review of these practices; further,
- 4 To advocate that drug product manufacturers be required to provide public notification in advance of significant price increases.
- 5

(Note: This policy would supersede ASHP policy 0814.)

Rationale

A healthy market for drug products increases patient access to drugs and lowers drug costs. ASHP recognizes several threats to the health of that market and advocates legislative, regulatory, and oversight solutions, including 1) reducing drug monopolies by incentivizing competition for additional generic drug market entrants, 2) targeting exclusivity protections to truly innovative products, and 3) appropriate federal review of anticompetitive practices by drug product manufacturers. ASHP 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. Payments to delay generic entry should be reviewed by the Federal Trade Commission because of their potentially anticompetitive nature and their possible violation of antitrust laws. ASHP also 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 sometimes abused to extend market exclusivity. Another solution advocated by ASHP is curbing misuse of REMS, which are sometimes 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. In addition to such a report, ASHP advocates that drug product manufacturers be required to provide public notification in advance of significant price increases.

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to amend ASHP policy 0814, Federal Review of Anticompetitive Practices by Drug Product Manufacturers, as follows (underline indicates new text):

To strongly oppose anticompetitive practices by manufacturers that adversely affect drug product availability and price; further,

To encourage appropriate federal review of these practices; further,

To advocate that manufacturers be required to provide public notification in advance of significant price increases.

In making its recommendation, the Advisory Panel suggested amending this policy due to recent drug price increases. Requiring early notification would enable health systems to proactively manage shortages and their budgets. The Panel was sensitive to the question of whether this would be anticompetitive in cases where there is a sole-source product and advised the Council to have further discussion related to this question. The Council agreed with

the suggested Advisory Panel's edits to the policy but recognized that defining terms like "significant" would be difficult. The Council was not as concerned over the issue of public notification on a sole-source product provided that proprietary contractual information among supply chain members would not be revealed.

7. Federal Quality Rating Program for Pharmaceutical Manufacturers

- 1 To advocate that the Food and Drug Administration (FDA) assign quality ratings to
- 2 pharmaceutical manufacturers based on the quality of their manufacturing processes,
- 3 sourcing of active pharmaceutical ingredients and excipients, selection of contract
- 4 manufacturers, and business continuity plans; further,

- 5 To advocate that the FDA consider offering incentives for manufacturers to participate in
- 6 the program.

Rationale

Shortages of critical drug products in hospitals and health systems continue to pose a significant threat to public health, and pharmacists and other clinicians are often challenged with locating supplies of life-saving or life-sustaining drug products at a moment's notice and with very few options to choose from. While the number of new shortages has fallen considerably since 2011, a number of drug products remain in short supply. Drug product shortages are often caused by a manufacturing problem (e.g., contamination) that halts production until the problem is resolved. To address the issue of quality in drug product manufacturing, the FDA has considered creation of a manufacturing quality initiative that would highlight companies that employ the best quality manufacturing processes by establishing a rating system that would assign a rating to companies based on their level of quality in the manufacturing process. This rating system could be made public to enable prospective customers to see which companies employ the best quality practices. Further, the rating system could serve as a basis for FDA to offer incentives to companies who consistently rate higher than competitors.

Background

Based upon a recent drug product shortages meeting among clinician groups, the FDA, American Hospital Association, and the Department of Health and Human Services, the Council brought forth new policy that would support the creation of a quality ratings program for drug manufacturers as a way to help prevent and mitigate drug product shortages. The plan would consist of FDA-applied ratings for drug manufacturers based on their manufacturing processes, with a specific focus on quality. The companies that demonstrate higher levels of manufacturing quality would receive higher ratings, resulting in more public confidence in that manufacturer's ability to make products.

8. Intravenous Fluid Manufacturing Facilities as Critical Public Health Infrastructure

- 1 To advocate that federal and state governments recognize intravenous fluid
- 2 manufacturing facilities as critical public health infrastructure.

Rationale

In the wake of hurricane Maria's impact on Puerto Rico in 2017, there has been rising interest in examining drug shortages from a national security perspective. The vulnerability of drug manufacturing on the island of Puerto Rico underscored a need to more closely evaluate the potential impacts of natural disasters on drug manufacturing and the production of critical pharmaceutical supplies. The Department of Homeland Security's list of key infrastructure includes public health infrastructure. ASHP advocates that public health infrastructure be defined to include manufacturing sites of intravenous fluids and that those sites be afforded the same protections as other critical infrastructure. Such protections should include an evaluation of manufacturing vulnerabilities such as geographic location, vulnerability of surrounding infrastructure such as roads or ports, and whether the company has developed business continuity plans or redundancies in manufacturing. Entities deemed critical public health infrastructure should be required to make necessary changes to ensure that manufacturing is not at risk for a supply disruption.

Background

The Council discussed the impacts of hurricane Maria on pharmaceutical manufacturing in Puerto Rico, notably on small-volume parenteral solutions. Given the severe shortages following the hurricane, the Council noted increased interest in examining drug shortages from a national security perspective. The Council concluded that one approach would be to advocate that the Department of Homeland Security designate intravenous fluid manufacturing facilities as public health infrastructure. The Council believes that such public health infrastructure should include manufacturing sites of intravenous fluids and should therefore be evaluated by risk of natural disasters or other risks to manufacturing capacity. Depending on the risk factors, manufacturers could be encouraged to establish backup plans in the event of a disaster.

9. Medical Devices

- 1 To advocate that the Food and Drug Administration (FDA) and manufacturers of drug
- 2 preparation, drug distribution, and drug administration devices and associated new
- 3 technologies ensure transparency, clarity, and evidence be provided on the intended use
- 4 of devices and technologies in all phases of the medication-use process; further,
- 5 To advocate that the FDA and device manufacturers ensure compatibility between the
- 6 intended use of any device and the drugs to be used with that device.

(Note: This policy would supersede ASHP policy 9106.)

Rationale

The lines between devices, drugs, and technology are blurring as new and innovative technologies combine drugs and devices. Because drugs and medical devices undergo different approval processes, it is important that compatibility between the intended use of any device and the drugs to be used with that device be ensured during the approval process so that unintended and possibly detrimental consequences do not occur. In addition, clinicians require information about the intended use of devices in all phases of the medication-use process in order to make the best-informed decisions about patient care.

Background

The Council reviewed ASHP policy 9106, Medical Devices, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Council did not agree with the Panel's recommendation to discontinue the policy, noting the importance of the policy and the gap in policy regarding transparency and technology that would be created. The Council voted to recommend amending policy 9106 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

~~To support public and private initiatives to clarify and define the relationship among drugs, devices, and new technologies in order to promote safety and effectiveness as well as better delivery of patient care.~~

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

The Council reviewed the recommendations of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel to discontinue this policy. The recommendation was based on existing ASHP policies (e.g., 1020, Role of Pharmacists in Safe Technology Implementation; 1313, Drug-Containing Devices; 1302, Interoperability of Patient Care Technologies) that the Panel believed covers the intent of the policy 9106. The Council discussed the issue at length and ultimately decided that those policies would not be sufficient to cover the issue in policy 9106. The Council further decided that an update to the policy language would be more appropriate rather than discontinuation.

10. ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems

- 1 To discontinue the ASHP Statement on Principles for Including Medications and
- 2 Pharmaceutical Care in Health Care Systems (Appendix B).

Background

The Council reviewed the statement and agreed with the recommendation by the Formulary Review Panel that the statement was redundant with other ASHP policy positions. The Panel and Council noted that the statement was originally developed to address advocacy needs during Clinton-era healthcare reform efforts and that its content came directly from ASHP policy positions. Although the Panel and Council recognized the value of a policy statement on healthcare reform, it was agreed that in such a rapidly changing policy landscape that ASHP policy positions are a more appropriate method for adopting and adapting policy to member needs. The Council also noted that ASHP had recently created the Board-approved [ASHP Principles on Healthcare Reform](#) successfully using the approach of collecting ASHP policy positions on the topic.

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.)

- Regulation of Automated Drug Dispensing Systems (9813)
- Licensure for Pharmacy Graduates of Foreign Schools (0323)
- Education, Prevention, and Enforcement Concerning Workplace Violence (0810)
- Regulation of Dietary Supplements (0811)
- Appropriate Staffing Levels (0812)
- Public Funding for Pharmacy Residency Training (0325)
- Pharmacists' Role in Immunization (1309)
- Regulation of Telepharmacy Services (1310)
- Regulation of Centralized Order Fulfillment (1311)

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has



created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Government Negotiation of Drug Prices

The sharp increase in drug prices jeopardizes patient access to drugs and places a severe strain on the healthcare system. High drug costs can impact patient outcomes by decreasing patient adherence due to financial burdens. Increased drug prices also place enormous budgetary pressure on healthcare organizations.

The Council discussed potential new policy on government negotiation of drug pricing in response to a recommendation from the June 2017 House of Delegates. Given both the controversial nature of this recommendation and the potential for unintended consequences, the Council decided that new policy was not appropriate at this time. However, the Council is recommending that ASHP sections and section advisory groups conduct additional research and discussion that could guide future policy.

The Council suggested that another option could be to develop a simple statement for the Board of Directors that expresses concerns over high drug prices, and exploring the possibility of developing a more in-depth statement at a later date that includes research, analysis, and policy recommendations.

Pharmacy Benefit Management (PBM) Transparency Regarding Direct and Indirect Remuneration (DIR) Fees

The Council discussed potential elements of a policy recommendation on the topic given that it has significant financial impact on health systems. While there was widespread agreement over the necessity of such a policy on DIR fees, Council members wondered whether the policy should be expanded to include more transparency over PBM rebates given by manufacturers and how that impacts pharmaceutical pricing. Mr. Hill volunteered to check with the Council on Pharmacy Management to determine the scope of their related agenda item for Policy Week, and Drs. Lee and Fox volunteered to work with Dr. Guharoy on drafting potential policy language for Policy Week.

Proposed Resolution on Specialty Drug Products

At its second June meeting, the House of Delegates voted to refer a resolution on FDA Criteria for Specialty Drug Products Available through Restricted Drug Distribution for further study by the Council on Public Policy. It was the consensus of the Council that empowering the FDA to define specialty drug products would not be advisable. The Council expressed concern that an FDA definition could invite abuse by manufacturers. If FDA develops criteria defining a specialty

drug, drug manufacturers could make their products fit the specified criteria, creating more specialty drugs and restricted distribution channels. The Council discussed whether a broadly agreed-upon definition would be helpful and what ASHP's role in developing such a definition should be. Although the Council generally supported the resolution's intent, the Council agreed with the Board of Directors that ASHP policy 1714, Restricted Drug Distribution, was a better means to achieve the outcome sought in the resolution, particularly that patient safety should be the sole criterion for determining whether restricted distribution is necessary.

Appendix A. ASHP Statement on Advocacy as a Professional Obligation

Position

ASHP believes that all pharmacists have a professional obligation to advocate on behalf of patients and the profession. Pharmacists should stay informed of issues that affect medication-related outcomes and advocate on behalf of patients, the profession, and the public. These issues may include legal, regulatory, financial, and other health policy issues, and this obligation extends beyond the individual practice site to their broader communities. ASHP recognizes that to fulfill this obligation, training and education is needed. ASHP urges all pharmacists to accept this responsibility and to be advocates both within and outside the profession, in the community, and in society as a whole to strengthen the care of our patients.

Role of Professional Organizations in Promoting Advocacy

Advocacy can be defined as an activity by an individual or group to plead a case, support a cause, or to recommend a course of action related to political, economic, social, institutional or patient-care issues. When attempting to define the advocacy responsibilities for pharmacy, it is instructive to examine the guidance from other healthcare professional organizations regarding advocacy.

One role professional organizations play is to help define the moral and ethical responsibilities of the profession. The American Medical Association (AMA) and the American Nurses Association (ANA) articulate how the members of those professions should be involved in advocacy efforts. The *AMA Code of Medical Ethics* states that “physicians, individually and collectively through their professional organizations and institutions, should participate in the political process as advocates for patients (or support those who do) so as to diminish financial obstacles to access health care” and that “the medical profession must work to ensure that societal decisions about the distribution of health resources safeguard the interests of all patients and promote access to health services.”¹ These statements emphasize several responsibilities for the physician outside care for individual patients. Physicians are explicitly urged to participate in the political process as advocates and to make sure societal decisions are in the interest of all patients. Simply providing excellent patient care to patients within the physician’s practice is not enough to meet the physician’s ethical obligations.

The *ANA Code of Ethics with Interpretive Statements* Provision 8 states that “[t]he nurse collaborates with other health professionals and the public to protect human rights, promote health diplomacy, and reduce health disparities,” which is further elaborated in Interpretive Statement 8.2 to mean that “[n]urses must lead collaborative partnerships to develop effective public health legislation, policies, projects and programs that promote and restore health, prevent illness, and alleviate suffering.”² Provision 9 emphasizes the important role of nursing professional organizations in advocacy: “The profession of nursing, collectively through its professional organizations, must ... integrate principles of social justice into nursing and health policy.”² One prominent nurse advocate has described advocacy as “the cornerstone of nursing – nurses advocate for patients, causes, and the profession. Our advocacy, motivated by moral and ethical principles, seeks to influence policies by pleading or arguing within political, economic, and social systems, and also institutions, for an idea or cause that can lead to decisions in resource allocation that promote nurses, nursing, and all of healthcare.”³

Advocacy as a Professional Obligation

Current ASHP policies encourage pharmacists to serve as advocates for their patients and the profession. For example, ASHP Policy 1114, Pharmacist Accountability for Patient Outcomes, states in part that ASHP and pharmacists should “promote pharmacist accountability as a fundamental component of pharmacy practice to other healthcare professionals, standards-setting and regulatory organizations, and patients.”⁴ The [ASHP Statement on Leadership as a Professional Obligation](#) notes that “the practice of effectively influencing the behavior of physicians, nurses, pharmacy technicians, interns, support staff, and others to optimize medication safety and patient outcomes constitutes successful leadership.”⁵ ASHP policy position 1501, Pharmacist Participation in Health Policy Development, clearly articulates the role pharmacists should play in developing health policy: “To advocate that pharmacists participate with policymakers and stakeholders in the development of health-related policies at the national, state, and community levels...”⁴ The [ASHP Statement on the Role of Health-System Pharmacists in Public Health](#) states that “health-system pharmacists should be involved in public health policy decision-making and in the planning, development, and implementation of public health efforts. Health-system pharmacists can improve public health by ... advocating for sound legislation, regulations, and public policy regarding disease prevention and management; and engaging in public health research.”⁶

ASHP not only encourages pharmacists to participate in advocacy efforts but believes that pharmacists have a professional and moral obligation to do so. That obligation stems from the covenantal relationship between the pharmacist and their communities described in the profession’s shared *Code of Ethics of the Pharmacist* and the *Oath of a Pharmacist*. The *Code of Ethics of a Pharmacist* states that “[a] pharmacist serves individual, community, and societal needs” and “seeks justice in the distribution of health resources.”⁷ While the Code makes clear that the primary obligation of a pharmacist is to individual patients, the pharmacist’s responsibility extends at times beyond the individual to the community and society. The specific instance provided in the language of the Code is the distribution of health resources, in which pharmacists are called upon to seek a just distribution. The *Oath of a Pharmacist*, which college of pharmacy graduates across the country swear to, reads in part:

- I will consider the welfare of humanity and relief of suffering my primary concerns.
- I will embrace and advocate changes that improve patient care.⁸

The pharmacist’s advocacy responsibilities are also evident in [ASHP Vision and Mission statements](#). The ASHP Vision is “that medication use will be optimal, safe, and effective for all people all of the time,” and the ASHP Mission states in part that “ASHP serves its members as their collective voice on issues related to medication use and public health.”⁹ The broad purview of these statements is reinforced by the [ASHP Statement on Professionalism](#), which implores pharmacists to “commit themselves to improving healthcare institutions not simply for the well-being of individual patients but for the benefit of society as a whole” and “to join forces with other healthcare providers and patients ... to attain the kind of healthcare system our patients deserve and our society demands.”¹⁰

These professionwide and ASHP policies, like those of our professional counterparts in medicine and nursing, are a clear statement of the professional obligation members of the

profession have to involve themselves in the policy-making process to advocate for the needs of patients, the profession, and the public, both within and outside healthcare settings.

Preparing Pharmacist Advocates

Pharmacy education at several different levels includes recommendations that learners develop advocacy skills. The Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)* include the following learning expectations for professional communications and public health, respectively:

- Analysis and practice of verbal, non-verbal, and written communication strategies that promote effective interpersonal dialog and understanding to advance specific patient care, education, advocacy, and/or interprofessional collaboration goals.
- Exploration of population health management strategies, national and community-based public health programs, and implementation of activities that advance public health and wellness.¹¹

These expectations demonstrate that pharmacy students will be taught strategies to be successful advocates for a range of topics, including population health management strategies. This approach to teaching pharmacy students about population health strategies and other means of advancing public health suggests that pharmacists, as well as students, should begin to think not just about their obligations to individual patients but also to use their training to impact the health of communities or society as a whole. There is a push for more of this type of training for pharmacy students. In 2016, the American Association of Colleges of Pharmacy (AACP) published [Public Health and the CAPE 2013 Educational Outcomes: Inclusion, Pedagogical Considerations and Assessment](#), which provides guidance to the pharmacy profession on methods to use the Center for the Advancement of Pharmacy Education (CAPE) 2013 outcomes to incorporate public health within college of pharmacy curricula and in co-curricular programs/activities and delineates public health-related course objectives for both didactic and experiential courses. Two of the paper's recommended competency areas for integration of public health into didactic Pharm.D. curricula are:

- Process of health policy-making (e.g., local, state, federal government).
- Methods for participation in the policy process (e.g., advocacy, advisory processes, opportunities and strategies to impact policy and public health problems).¹²

Pharmacy residency training also incorporates advocacy. The [Required Competency Areas, Goals, and Objectives for Postgraduate Year One \(PGY1\) Pharmacy Residencies](#) states that one of the criteria for demonstrating "personal, interpersonal, and teamwork skills critical for effective leadership" is that a resident "effectively expresses benefits of personal profession-wide leadership and advocacy."¹³

Conclusion

ASHP believes pharmacists have a moral and ethical professional obligation to advocate for "changes that improve patient care"⁸ as well as "justice in the distribution of health resources."⁷ Specific ASHP policies on various aspects of healthcare, population health, and

public health stem from this general obligation. To meet this professional obligation, pharmacist advocates will need appropriate training and education.

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Appendix B. ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems

Introduction

The United States government, individual state governments, and private health care systems are moving toward reforming the way that they provide health care to their citizens or beneficiaries. As they do so, policy makers must improve their medication-use systems to address problems of access, quality, and cost of medicines and pharmaceutical care services. This document offers principles for achieving maximum value from the services of the nation's pharmacists.

Although pharmaceuticals and pharmaceutical care are among the most cost-effective methods of health care available, there is evidence that the public is not currently realizing the full potential benefit from these resources. Illnesses related to improper medication use are costing the health care systems in the United States billions of dollars per year in patient morbidity and mortality. Pharmacists are prepared and eager to help other health providers and patients prevent and resolve medication-related problems, and health care systems should facilitate and take advantage of pharmacists' expertise.

These principles are offered to guide health policy makers in their deliberations concerning the inclusion of medications and pharmacists' services in health care systems.

Principles

Principle I. Health care systems must make medications available to patients and provide for pharmaceutical care, which encompasses pharmacists' health care services and health promotional activities that ensure that medications are used safely, effectively, and efficiently for optimal patient outcomes.

Principle II. Careful distinction must be made between policies that affect pharmacist reimbursement and policies that affect pharmacist compensation. Health care systems must reimburse pharmacists for the medications they provide patients (including the costs of drug products, the costs associated with dispensing, and related administrative costs). Health care systems also must compensate pharmacists for the services and care that they provide to patients, which result in improved medication use and which may not necessarily be associated with dispensing.

Principle III. Patients differ in their needs for pharmaceutical care services. The method of compensating pharmacists for their services must recognize the value of the different levels and types of services that pharmacists provide to patients based on pharmacists' professional assessments of patients' needs.

Principle IV. Pharmacists must be enabled and encouraged to use their professional expertise in making medication related judgments in collaboration with patients and health care colleagues. Health care systems must not erect barriers to pharmacists' exercising professional judgments; nor should health care systems prescribe specific services or therapies for defined types of patients.

Principle V. Pharmacists should have access to relevant patient information to support their professional judgments and activities. Pharmacists should be encouraged and permitted

to make additions to medical records for the purpose of adding their findings, conclusions, and recommendations. Pharmacists will respect the confidential nature of all patient information.

Principle VI. Health care systems must be designed to enable, foster, and facilitate communication and collaboration among pharmacists and other care providers to ensure proper coordination of patients' medication therapies.

Principle VII. Quality assessment and assurance programs related to individual patient care should be implemented at local levels through collaborative efforts of health care practitioners rather than through centralized bureaucracies. Quality assessment and assurance procedures for medication use (such as pharmacy and therapeutics committees, formulary systems, drug-use evaluation programs, and patient outcomes analyses) are most effective when the professionals who care for covered patients are involved in the design and implementation of the procedures. Moreover, such programs must recognize local variations in epidemiology, demography, and practice standards. Information related to quality assessment and assurance activities must be held in confidence by all parties.

Principle VIII. Demonstration projects and evaluation studies in the delivery of pharmaceutical care must be enabled, fostered, and implemented. New services, quality assessment and assurance techniques, and innovative medication delivery systems are needed to improve the access to and quality of medication therapy and pharmaceutical care while containing costs.

Principle IX. Health care policies that are intended to influence practices of those associated with pharmacy, such as the pharmaceutical industry or prescribers, should address those audiences directly rather than through policies that affect reimbursement, compensation, or other activities of pharmacists.

This statement was reviewed in 2012 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Approved by the ASHP Board of Directors, November 18, 1992, and by the ASHP House of Delegates, June 7, 1993. Developed by a committee of the Joint Commission of Pharmacy Practitioners and subsequently reviewed and approved by the ASHP Council on Legal and Public Affairs.

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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.

Stephen F. Eckel, *Board Liaison*

Council Members

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Vicki Basalyga, *Secretary*

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

- 1 To encourage continued research on and development of orphan drug products; further,
- 2 To advocate for the use of innovative strategies and incentives to expand the breadth of
- 3 rare diseases addressed by this program; further,
- 4 To encourage postmarketing research to support the safe and effective use of these drug
- 5 products for approved and off-label indications; further,
- 6 To urge health policymakers, payers, and pharmaceutical manufacturers to develop
- 7 innovative ways to ensure patient access to orphan drug products; further,
- 8 To urge federal review to evaluate whether orphan drug status is being used
- 9 inappropriately to extend patents and decrease competition, reducing patient access.

(Note: This policy would supersede ASHP policy 1413.)

Rationale

The U.S. Orphan Drug Act of 1983 and similar programs in other countries have greatly expanded the number of therapies available to treat rare diseases through the use of financial and other incentives that encourage drug manufacturers to develop medications for limited



patient populations. Despite the overall success of orphan drug programs, concerns have been raised about the breadth of drugs approved through these mechanisms. Although there are more than 7,000 designated orphan diseases in the United States, oncology drugs represent approximately 33 percent of all orphan drug approvals. ASHP believes that there is a significant need to develop a more comprehensive approach to orphan drug development in order to encourage drug manufacturers to expand the breadth of rare conditions treated by these therapies.

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

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

There are additional challenges regarding patient access to orphan drugs. There is a need for more emphasis on increasing patient access and addressing 340B issues, especially with critical access facilities. Orphan drug development and marketing in the U.S. is concentrated in a few therapeutic areas. Despite the increase in the number of orphan drugs approved by the Food and Drug Administration, the unmet needs of patients with rare diseases provide evidence that the current incentives are not efficiently stimulating orphan drug development. There is need to balance economic incentives to stimulate the development and marketing of orphan drugs without jeopardizing patients' access to treatment.

Background

The Council reviewed ASHP policy 1413, Ensuring Effectiveness, Safety, and Access to Orphan Drug Products, on the recommendation of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel and voted to recommend amending the policy as follows (underscore indicates new text):

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

To advocate for the use of innovative strategies and incentives to expand the breadth of

rare diseases addressed by this program; further,

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

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

To urge federal review to evaluate whether orphan drug status is being used inappropriately to extend patents and decrease competition, reducing patient access.

The Council concurred with the Panel's concerns and supported the language addition to policy 1413 and added to the rationale to support the updated clause.

In addition, the Council also discussed a requested amendment to ASHP policy 1413 from the House of Delegate to include a clause that advocates being more inclusive of educating pharmacists and other healthcare providers about rare (orphan) diseases. The Council acknowledged that many healthcare providers may not be familiar with rare diseases but that ASHP could meet this need through its various educational avenues.

2. Rational Use of Medications

- 1 To recognize that irrational medication use is inappropriate and can result in patient
- 2 harm and increased overall healthcare costs; further,

- 3 To support and promote evidenced-based prescribing for indication, efficacy, safety,
- 4 duration, cost, and suitability for the patient; further,

- 5 To advocate that pharmacists lead interprofessional efforts to promote the rational
- 6 use of medications, including engaging in strategies to monitor, detect, and address
- 7 patterns of irrational medication use in patient populations.

(Note: This policy would supersede ASHP policy 1312.)

Rationale

The World Health Organization (WHO) identifies that rational use of medications requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." The overuse, underuse, or misuse of medicines results in wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include use of too many medicines per patient, inappropriate use of antimicrobials, inadequate dosage, overuse of injections when oral formulations would be more appropriate, failure to prescribe in accordance with clinical guidelines, inappropriate self-medication, decreased access to medicines, and nonadherence to dosing regimens. These actions can negatively affect the

quality of patient care, raise healthcare costs, and increase the number of adverse reactions and events, and may cause adverse reactions or negative psychosocial effects.

Strategies to address irrational medication use can be characterized as educational, managerial, economic, or regulatory in nature. Furthermore, the WHO advocates 12 key interventions to promote more rational use of medications:

- establishment of a multidisciplinary national body to coordinate policies on medication use;
- use of clinical guidelines;
- development and use of national essential medications list;
- establishment of drug and therapeutics committees in districts and hospitals;
- inclusion of problem-based pharmacotherapy training in undergraduate curricula;
- continuing in-service medical education as a licensure requirement;
- supervision, audit, and feedback;
- use of independent information on medications;
- public education about medications;
- avoidance of perverse financial incentives;
- use of appropriate and enforced regulation; and
- sufficient government expenditure to ensure availability of medications and staff.

These recommendations are echoed by the Joint Commission of Pharmacy Practitioners, whose tenets of the pharmacists' patient care process include the collection of necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient; assessment of information collected and analysis of the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care; development of an individualized patient-centered care plan, in collaboration with other healthcare professionals and the patient or caregiver that is evidence-based and cost-effective; implementation of the care plan in collaboration with other healthcare professionals and the patient or caregiver; and monitoring and evaluation of the effectiveness of the care plan and modification of the plan in collaboration with other healthcare professionals and the patient or caregiver as needed.

Background

The Council discussed this topic as a part of the sunset review of ASHP policy 1312, Medication Overuse, which reads:

To define medication overuse as use of a medication when the potential risks of using the drug outweigh the potential benefits for the patient; further,

To recognize that medication overuse is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To advocate that pharmacists take a leadership role in interprofessional efforts to

minimize medication overuse.

The Council recognized that there are significant costs, adverse effects, and safety events related not only to medication overuse but also underuse, misuse, and omission. The WHO-recommended key interventions touched upon many of the topics brought up by the Council and already align with common areas where pharmacists or pharmacy departments are already participants. The Council suggested discontinuing policy 1312 and replacing it with the recommended policy language.

3. Responsible Medication-related Clinical Testing and Monitoring

- 1 To recognize that overuse of clinical testing is an increasingly recognized problem in
- 2 practice that can lead to unnecessary costs, waste, and patient harm; further,

- 3 To encourage pharmacists to engage in interprofessional efforts to promote the
- 4 appropriate but judicious use of testing, monitoring, assessment of clinical progress,
- 5 dose adjustment, and discontinuation of medication therapy, where appropriate;
- 6 further,

- 7 To promote research that evaluates pharmacists' contributions and identifies
- 8 opportunities for the appropriate use of procedures and test ordering in healthcare
- 9 systems.

Rationale

As the prevalence of collaborative practice grows and as pharmacist care expands into direct patient care services, so too do the responsibilities held by these practitioners. In many institutions, pharmacists' responsibilities now include ordering blood draws as a part of initiating a medication regimen, assessing drug levels, monitoring for adverse effects, or ordering imaging such as ultrasound for evaluating a deep vein thrombosis or an electrocardiogram to evaluate a QTc interval.

Overuse of medical care is a long-recognized problem in clinical medicine, and more spending and treatment do not translate into better patient outcomes and health. The number of articles on overuse nearly doubled from 2014 to 2015, indicating that awareness of overuse is increasing, despite little evidence of improved practice, which may mean that the overuse of diagnostic tests and lab monitoring is leading to patient harm and could outweigh benefits. Healthcare continues to be enthralled by high-technology innovation, including both therapies and tests. Once practice norms are established, clinicians are slow to de-implement services, even those that are found to be potentially dangerous. Reasons for excessive ordering of tests by healthcare providers include defensive behavior, fear, uncertainty, lack of experience, the use of protocols and guidelines, routine clinical practice, inadequate educational feedback, and clinician's lack of awareness about the cost of examinations. Inappropriate testing causes unnecessary patient discomfort, entails the risk of generating false-positive results, leads to

overloading of diagnostic services, wastes valuable healthcare resources, and is associated with other inefficiencies in healthcare delivery, undermining the quality of health services.

[Choosing Wisely](#) is a national program designed to help raise provider and public awareness and garner support for appropriate test utilization, with the goal of promoting conversations between providers and patients about choosing appropriate care in order to reduce both harm and waste. In 2016, ASHP [announced its partnership](#) with the ABIM Foundation on the Choosing Wisely campaign and is the first pharmacy organization to participate in the campaign.

Background

The Council discussed this topic as a part of the sunset review of ASHP policy 1312, Medication Overuse. Many Council members have some level of ability to order labs and other procedures for diagnosis, monitoring, and guidance of medication therapy. Council members also shared experiences where lab draws were unnecessary, caused patient harm, and contributed to waste.

4. Clinical Practice and Application on the Use of Biomarkers

- 1 To promote appropriate, evidence-based use of biomarkers in clinical practice;
- 2 further,
- 3 To encourage research that evaluates the clinical and safety implications of
- 4 biomarkers in the care of patients and to guide clinical practice; further,
- 5 To promote Food and Drug Administration (FDA) approved qualified medication
- 6 biomarkers in drug development, regulation, and use in clinical practice; further,
- 7 To foster the development of timely and readily available resources about
- 8 biomarkers and their evidenced based application in practices.

Rationale

The National Institutes of Health Biomarkers Definitions Working Group [defined a biomarker](#) as “a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.” In comparison to a clinical endpoint, a biomarker is strictly objective and quantifiable, whereas a clinical endpoint reflects the subject’s well-being and health status from the subject’s perspective. As [defined by the FDA](#), a biomarker is “a defined characteristic that is measured as an indicator of normal biological processes, or responses to an exposure or intervention, including therapeutic interventions.” The FDA classifies biomarkers in the following categories: susceptibility/risk biomarker, diagnostic biomarker, monitoring biomarker, prognostic biomarker, predictive biomarker, pharmacodynamic/response biomarker, and safety biomarker.

Further, the FDA and Center for Drug Evaluation and Research are involved in regulating biomarkers in drug development, regulation, and use in clinical practice. Under the FDA [Biomarker Qualification Program](#), researchers can request qualification of a biomarker in the use of drug development. The FDA's involvement in biomarker qualifications allows for the development of a regulatory process to investigate the safety and efficacy of biomarkers. Innovative and newly discovered biomarkers are investigated or found unexpectedly in clinical research. Recently published articles demonstrate newly discovered biomarkers that potentially show clinical efficacy; however, there is debate about how to conduct further research to establish a biomarker's clinical efficacy.

This growth in discovery and application of established biomarkers in practice presents several practice issues, including use of recognized biomarkers, collaborating with practitioners concerning newly discovered or rising biomarkers, conducting research on the outcomes of the use of various biomarkers, and integrating use of biomarkers into practice.

Background

Practitioners are seeing more and more data published on using biomarkers in various areas of practice including utilization to in treatment protocols as well as dual roles in diagnostic and monitoring.

5. Medication Overuse

- 1 To discontinue ASHP policy 1312 Medication Overuse, which reads:
- 2 To define medication overuse as use of a medication when the potential risks of
- 3 using the drug outweigh the potential benefits for the patient; further,
- 4 To recognize that medication overuse is inappropriate and can result in patient
- 5 harm and increased overall healthcare costs; further,
- 6 To advocate that pharmacists take a leadership role in interprofessional efforts to
- 7 minimize medication overuse.

Background

The Council reviewed this policy as a part of sunset review and concluded that, although aspects of medication overuse still contribute to patient care aspects within practice, such as overuse of antimicrobials and opioids, there are other ASHP policies that address these contemporary issues (1702, Reduction of Unused Prescription Drug Products; 1722, Pain Management; 1614, Controlled Substance Diversion and Patient Access; 1603, Stewardship of Drugs With Potential for Abuse; 1604, Appropriate Use of Antipsychotic Drug Therapies; and the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control). Furthermore, the Council concluded that while overuse is

inappropriate and can cause patient harm, there are also significant issues with underuse and misuse of medications and medication classes as well, and that a more comprehensive policy (recommended above) that would supersede this policy is needed.

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.)

- Drug-Containing Devices (1313)
- DEA Scheduling of Controlled Substances (1315)

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

ASHP Therapeutic Position Statement on Use of Antipsychotic Medications in the Treatment of Adults with Psychotic Disorders

The Council reviewed the ASHP Therapeutic Position Statement on the Use of Antipsychotic Medications in the Treatment of Adults with Psychotic Disorders. The Council appreciated the expansion of the Therapeutic Position Statement from second generation antipsychotics to all classes of antipsychotics but could not approve the therapeutic position statement in its current draft. The Council is requesting clarification in specific areas of the document, including

the need to consider stroke prophylaxis in all elderly patients receiving antipsychotic drugs, particularly high-risk patients as this is not a practice members were familiar with; clarification on the pharmacogenomics aspects: use of QTc prolongation; and a request for a table in the document on the side of effects of these medications. The Council has provided in writing their questions and concerns for this document.

Antipsychotic Use in the Emergency Department (ED)

The Council discussed the care and medication issues that patients with psychiatric disease encounter in the ED and the challenges pharmacists face in treating this high-risk population. Given the lack of patient beds, extended period of time patients often spend in the ED, difficulty in assessing patients due to effects of medications that are sometimes needed to protect patients and staff, there is a definite need to help members with this area of practice. The Council acknowledged that the Section of Clinical Specialists and Scientists Section Advisory Group on Emergency Care is updating the ASHP Statement on Pharmacy Services to the Emergency Department and the ASHP Guidelines on Emergency Medicine Pharmacist Services and recommended that these revisions include considerations for psychiatric patients.

The Council also recognized that psychiatric patients are not only treated in the ED but also in outpatient and inpatient areas, and discussed the lack of pharmacists willing or able to precept students and residents in this practice area. Potential ways that ASHP could assist in meeting this need would be to develop a traineeship or certificate program; education through its various channels, including the Midyear Clinical Meeting; webinars; an article in *AJHP*; and possibly a web-based resource center.

Therapeutic Use of Probiotics

The Council discussed at length the difficulty of how to classify probiotics, as they are components of food items, dietary supplements, nutraceuticals, and other products in the marketplace and healthcare. The Council also addressed how these products and different strains are used in practice.

The Council determined that the majority of formulations and issues with pre- and probiotics did fall under existing ASHP policy and did not feel strongly enough that a separate policy is needed to address these issues. The Council did recommend that when the ASHP Statement on the Use of Dietary Supplements is updated, probiotics be included. Due to their variety, the Council recommended that ASHP provide education on the topic, as some strains have been studied and proven effective, through its various avenues of education, particularly an update to the March 15, 2010, *AJHP* article on probiotics, and a therapeutic debate topic at the Midyear Clinical Meeting. There was also interest in surveying the ASHP membership to discern how probiotics are being used so that ASHP can address member needs on this topic.

Biome Transfers

The Council reviewed the clinical aspects of biome transfers, including vaginal biome transfer and the more commonly used fecal matter transplant (FMT). With the success of FMT in the treatment of resistant *C. difficile* infections, there has been an expanding interest in the treatment of other diseases, including other gastrointestinal maladies, diabetes, obesity, neurologic disorders, and autism, with some or few studies on these emerging areas.

The Council felt that because FMT is an established treatment and has both therapeutic and practice elements that the Council on Pharmacy Practice should evaluate the need for a policy, as many of the topics discussed are outside the purview of the Council on Therapeutics. Operation logistics discussed included screening and management of donors, protocols including hazardous waste and biohazardous handling of fecal matter, storage and handling, and the role of the pharmacist. Council members who perform FMT at their institutions state that the pharmacy department does not have an integral role, as the transfer is done by a specialty service, such as the gastrointestinal specialist. The Council also recommended education through ASHP's various educational arms.

ASHP Therapeutic Position Statement on the Use of Second-Generation Antipsychotic Medications in the Treatment of Adults with Schizophrenia and Schizoaffective Disorders

The Council discussed the ASHP Therapeutic Position Statement on the Use of Second-Generation Antipsychotic Medications in the Treatment of Adults with Schizophrenia and Schizoaffective Disorders (the TPS). The Council reviewed the recommended changes that were suggested upon their last review and noted typographical errors, nomenclature discrepancies, and referencing mistakes. The Council agreed that the information that was specific to antipsychotics appeared to be accurate and suggestions made from the last review were incorporated into the TPS. However, there was considerable concern with some of the cardiac and pharmacogenomic information in the TPS that requires change before the Council can approve it. The Council agreed to forward their comments to the authors for their review and consideration.

ASHP Therapeutic Position Statement on the Role of Pharmacotherapy in Preventing Venous Thromboembolism in Hospitalized Patients

The Council discussed the ASHP Therapeutic Position Statement on the Role of Pharmacotherapy in Preventing Venous Thromboembolism in Hospitalized Patients (the TPS). The Council agreed that the TPS no longer reflects current practice due to newer classes of drugs now available to treat this patient population. Upcoming and recently published trials with these new drugs classes will need to be incorporated into the statement, particularly in

the sections that address risk-assessment models, hip and knee replacement therapies, special populations, reversal, and extended duration therapy in the medically ill hospitalized patients. Despite these shortcomings, the guidelines still provide good advice on many areas of practice. The Council agreed that the TPS required revision and that ASHP staff would reach out to subject matter experts for updating.

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.

Linda S. Tyler, *Board Liaison*

Council Members

Nicole Clark, *Chair* (Massachusetts)
Whitney White, *Vice Chair* (Alabama)
David Gregory (Mississippi)
Seena Haines (Mississippi)
Tadd Hellwig (South Dakota)
Heather Jones, *New Practitioner* (Wisconsin)
Patricia Knowles (Georgia)
Krystal Moorman (Utah)
Marvin Ortiz, *Student* (California)
Kristine Parbuoni (California)
Rebecca Taylor (Ohio)
Lanita White (Arkansas)
Erika Thomas, *Secretary*

1. Clinician Well-being and Resilience

- 1 To acknowledge that the healthcare workforce encounters unique stressors
- 2 throughout their education and careers that contribute to burnout; further,

- 3 To affirm that burnout adversely affects an individual's well-being and healthcare
- 4 outcomes; further,

- 5 To encourage healthcare organizations to develop programs aimed at prevention,
- 6 recognition, and treatment of burnout, and to support participation in these
- 7 programs; further,

- 8 To encourage individual pharmacists to embrace resilience and well-being as a
- 9 personal responsibility that should be supported by organizational culture; further,

- 10 To foster research on stress, burnout, and well-being, especially in pharmacy;
- 11 further,

- 12 To collaborate with other professions to identify effective preventive and treatment
- 13 strategies at an individual, organizational, and system level.

Rationale

Burnout is a syndrome characterized by a high degree of emotional exhaustion, high depersonalization (e.g., cynicism), and a low sense of personal accomplishment from work due to both internal and external factors. More than half of U.S. physicians show symptoms of burnout, which is nearly twice as high as other U.S. workers, even after controlling for work hours and other factors. Between 2011 and 2014, the prevalence of burnout increased by 9% among physicians while remaining stable in other U.S. workers. The American Foundation for Suicide Prevention reports that 300-400 physicians commit suicide each year, approximately one per day. Nurses show a similarly high prevalence of burnout and depression. A 2007 study reported that 22-35% of nurses had a high degree of emotional exhaustion. A survey at Duke University Hospital found that 20% of pharmacists were at risk for burnout. And although less is known about other members of the healthcare team, data suggest a similar prevalence of burnout among pharmacy technicians, nurse practitioners, and physician assistants.

Stress in our clinical learning environment can affect all healthcare learners, with negative outcomes ranging from poor well-being to substance abuse to depression, even suicide. Two New York City medical residents committed suicide in a 2-month period during the 2014–15 residency year. One review estimates that nearly 29% of medical residents suffer from depression or depressive symptoms, well above the 16% estimated prevalence in the general population. One study has shown that pharmacy residents exhibit high levels of perceived stress, especially those who work more than 60 hours per week, and perceived stress is highly correlated to negative effects.

ASHP joined the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience in 2017. The goals of the Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. Clinician burnout is a concern because, in addition to clinician suffering, clinician burnout has been associated with increased rates of medical errors, healthcare-associated infection, and patient mortality. Clinician burnout also decreases patient satisfaction and healthcare workforce productivity. Students in the health professions are also susceptible to burnout.

Studies suggest that burnout is a problem of the whole healthcare organization, rather than individuals, which indicates that pharmacists, along with other healthcare professionals and administrators, have a role in researching and solving the problem. To be successful, interventional programs must promote prevention, recognition, and treatment of burnout, and healthcare organizations must foster a culture that supports not just participation in these programs but a sense of personal responsibility for developing and maintaining resilience.

Providing patient care is meaningful and purposeful work. A healthcare organization with a resilient workforce will provide the best healthcare outcomes.

Background

The Council considered this topic as ASHP begins its participation in the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience. Although ASHP has policy on pharmacists as second victims (ASHP policy 1524) and pharmacy fatigue (ASHP policy 0504), ASHP policy has not addressed the increasingly important issues of burnout, well-being, and

resilience directly. The recommended policy will promote ASHP efforts on these topics and support its work in the Action Collaborative.

2. Student Pharmacist Drug Testing

- 1 To advocate for the use of pre-enrollment, random, and for-cause drug testing
- 2 throughout pharmacy education and prior to pharmacy practice experiences, based
- 3 on defined criteria with appropriate testing validation procedures; further,

- 4 To encourage colleges of pharmacy to develop policies and processes to identify
- 5 impaired individuals; further,

- 6 To encourage colleges of pharmacy to facilitate access to programs for treatment
- 7 and recovery; further,

- 8 To encourage colleges of pharmacy to use validated testing panels that have
- 9 demonstrated effectiveness detecting commonly misused, abused, or illegally used
- 10 substances.

Rationale

Persons 18-25 years of age have the highest prevalence of prescription drug misuse among all age groups. Moreover, there is growing evidence that prescription drug misuse has been increasing among U.S. college students, and it is second to marijuana as the most common form of substance abuse. Pharmacy professionals and students are entrusted with the health, safety, and welfare of patients. They have access to controlled substances and confidential information, and operate in settings that require the exercise of good judgment and ethical behavior. Thus, an assessment of a student pharmacist's possible impairment, which could diminish his or her capacity to function in such a setting, is imperative to promote the highest level of integrity in healthcare services. ASHP recognizes that drug testing student pharmacists, whose responsibilities may bring them into contact with controlled substances, is an essential element of diversion prevention programs. Pre-enrollment, random, and 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 addiction recovery program, as outlined in the [ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance](#).

Background

The Council considered this topic at the suggestion of the ASHP Pharmacy Student Forum. In 2017, the House of Delegates approved ASHP policy 1717, Drug Testing, which reads:

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 Pharmacy Student Forum Executive Committee drafted the policy recommendation after recognizing the need for a policy to advocate for and encourage all colleges of pharmacy to employ drug testing prior to and throughout enrollment at the college.

3. Collaboration on Experiential Education

- 1 To encourage practitioner contributions to pharmacy education; further,
- 2 To encourage pharmacists and pharmacy leaders to recognize their professional
3 responsibility to contribute to the development of new pharmacy practitioners;
4 further,
- 5 To promote collaboration of experiential teaching sites with the colleges of
6 pharmacy (nationally or regionally), for the purpose of fostering preceptor
7 development, standardization of experiential rotation schedule dates and evaluation
8 tools, and other related matters; further,
- 9 To encourage colleges of pharmacy and health systems to define and develop
10 collaborative organizational relationships that support patient care and advance the
11 missions of both institutions in a mutually beneficial manner.

(Note: This policy would supersede ASHP policies 0315 and 0804.)

Rationale

As stated in the [ASHP Statement on Professionalism](#), one of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission. Because the principles of institutional pharmacy practice are not emphasized in typical pharmacy curricula, professional socialization is especially important for pharmacists who practice in those settings. The experiential education experience of student pharmacists is a partnership between colleges of pharmacy and the experiential teaching sites. Collaboration between the colleges of pharmacy and experiential training sites on preceptor development, standardized rotation schedule dates, evaluation tools, and other materials helps to assure the best possible experience for student pharmacists, preceptors, and the experiential education site. In addition, collaboration allows both entities to fulfill their missions through mutually beneficial activities, improving patient outcomes, and helping students and their institutions achieve educational and research objectives.

Background

The Council reviewed ASHP policy 0804, Collaboration Regarding Experiential Education, and ASHP policy 0315, Practice Sites for Colleges of Pharmacy, as part of sunset review and voted to recommend amending policy 0804 as follows (underscore indicates new text):

To encourage practitioner input in pharmacy education; further,

To encourage pharmacists and pharmacy leaders to recognize their professional responsibility to contribute to the development of new pharmacy practitioners; further,

To promote collaboration of experiential teaching sites with the colleges of pharmacy (nationally or regionally), for the purpose of fostering preceptor development, standardization of experiential rotation schedule dates and evaluation tools, and other related matters; further,

To encourage colleges of pharmacy and health systems to define and develop collaborative organizational relationships that support patient care and advance the missions of both institutions in a mutually beneficial manner.

The Council combined the policies by adding much of the text of ASHP policy 0315, Practice Sites for Colleges of Pharmacy, which reads as follows:

To encourage practitioner input in pharmacy education; further,

To encourage that institutional and health-system environments be used as sites for experiential training of pharmacy students; further,

To encourage colleges of pharmacy and health systems to define and develop appropriate organizational relationships that permit a balance of patient care and service, as well as educational and research objectives, in a mutually beneficial manner; further,

To include the administrative interests of both the health system and the college of pharmacy in defining these organizational relationships to ensure compatibility of institutional (i.e., health system or university) and departmental (i.e., pharmacy department and department in the college) objectives; further,

To encourage pharmacists and pharmacy leaders to recognize that part of their professional responsibility is the development of new pharmacy practitioners.

4. Promoting the Image of Pharmacists and Pharmacy Technicians

- 1 To promote the professional image of pharmacists and pharmacy technicians who work in
- 2 acute and ambulatory settings to the general public, public policymakers, payers, other
- 3 healthcare professionals, and healthcare organization decision-makers; further,
- 4 To provide ASHP information and recruitment materials highlighting opportunities for
- 5 pharmacy careers in acute and ambulatory settings.

(Note: This policy would supersede ASHP policy 0703.)

Rationale

The success of ASHP's advocacy efforts relies on public perception of the pharmacists, student pharmacists, and pharmacy technicians we represent. Promoting the image pharmacy, which consistently ranks among the [most trusted professions](#), is an ongoing priority for ASHP. In addition, as stated in the [ASHP Statement on Professionalism](#), one of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission. The recruitment of pharmacists and pharmacy technicians begins in high school or even earlier, when students are exploring potential careers. ASHP is committed to highlighting opportunities for pharmacy careers in acute and ambulatory care settings to maintain a pool of quality candidates for those careers.

Background

The Council reviewed ASHP policy discussed ASHP policy 0703, Image of and Career Opportunities for Hospital and Health-System Pharmacists, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To ~~sustain and enhance the public information program promoting~~ promote the professional image of ~~hospital and health system~~ pharmacists and pharmacy technicians who work in acute and ambulatory settings to the general public, public policymakers, payers, other healthcare professionals, and ~~hospital and health system~~ healthcare organization decision-makers; further,

To provide ASHP information and recruitment materials ~~identifying~~ highlighting opportunities for pharmacy careers in ~~hospitals and health systems~~ acute and ambulatory settings.

5. Practice Sites for Colleges of Pharmacy

- 1 To discontinue ASHP policy 0315, Practice Sites for Colleges of Pharmacy, which
- 2 reads:
 - 3 To encourage practitioner input in pharmacy education; further,
 - 4 To encourage that institutional and health-system environments be used as sites
 - 5 for experiential training of pharmacy students; further,
 - 6 To encourage colleges of pharmacy and health systems to define and develop
 - 7 appropriate organizational relationships that permit a balance of patient care and
 - 8 service, as well as educational and research objectives, in a mutually beneficial
 - 9 manner; further,
 - 10 To include the administrative interests of both the health system and the college
 - 11 of pharmacy in defining these organizational relationships to ensure compatibility
 - 12 of institutional (i.e., health system or university) and departmental (i.e., pharmacy
 - 13 department and department in the college) objectives; further,
 - 14 To encourage pharmacists and pharmacy leaders to recognize that part of their
 - 15 professional responsibility is the development of new pharmacy practitioners.

Background

The Council determined to discontinue ASHP policy 0315 and revise ASHP policy 0804 by including portions of policy 0315 in the new policy recommendation.

6. Pharmacy Practice Training Models

- 1 To promote pharmacy practice training models that: (1) provide experiential and
- 2 residency training in interprofessional patient care; (2) use the knowledge, skills,
- 3 and abilities of student pharmacists and residents in providing direct patient care;
- 4 and (3) promote use of the pharmacist layered learning model; further,
- 5 To support the assessment of the impact of these pharmacy practice training
- 6 models on the quality of learner experiences and patient care outcomes.

(Note: This policy would supersede ASHP policy 1316.)

Rationale

Pharmacy practice training models are continually evolving. The ideal training model includes characteristics such as flexibility to be useful in all patient care settings, providing patient care

through an interprofessional team, and allowing team members to practice at the top of their licenses. Many healthcare organizations are successfully employing the layered learning approach to residency and student pharmacist training, in which a pharmacist oversees multiple residents, students, and sometimes generalist pharmacists. Each member of this pharmacy team is integrated into a patient care team, with specific roles and responsibilities, but each also has accountability to the supervising pharmacist. The layered learning model may be more practical in larger institutions, which have more staff, residents, and students than smaller hospitals. It is important to individualize the training program to the practice site and its corresponding practice model.

Background

The Council reviewed ASHP policy 1316, Pharmacy Resident and Student Roles in New Practice Models, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To promote pharmacy practice ~~and~~ training models that: (1) provide experiential and residency training in ~~team-based~~ interprofessional patient care; (2) ~~recognize and utilize~~ use the skills, ~~and~~ knowledge, and abilities of student pharmacists and residents in providing direct patient care ~~services~~; and (3) promote use of the pharmacist layered learning model ~~augment the patient care services of pharmacists through expanded roles for residents as practitioner learners; and (4) where appropriate, utilize an approach to learning and service in which a supervising pharmacist oversees the services of students, residents, and other pharmacists providing direct patient care;~~ further,

To support the assessment of the impact of these pharmacy practice ~~and~~ training models on the quality of learner experiences and patient care outcomes.

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.)

- Education and Training in Healthcare Informatics (1317)

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Graduating Student Survey

The Council discussed the American Association of Colleges of Pharmacy [2017 Graduating Student Survey Reports](#) (the 2017 Graduating Student National Summary Report, 2017 Graduating Student Public School Summary Report, and the 2017 Graduating Student Private School Summary Report). Council members discussed several survey findings, including a difference in ranking of introductory pharmacy practice experiences (IPPE) versus advanced pharmacy practice experiences (APPE) rotations, and concluded that this may be a reflection of student pharmacists not understanding how IPPE rotations fit into the educational process and the need to continue incorporating teaching innovations, such as live experiences or simulation-based experiences, into the classroom.

Residency Program Accreditation: Meeting the 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. Dr. Silvester shared information on ASHP-accredited pharmacy residency growth in the last year and noted that 26 programs to date have been added and that there has been a 17% growth in the number of residency programs over two years. It was also noted that although the absolute number of pharmacy graduates is decreasing, the number of graduates seeking a residency has increased approximately 30%. Additionally, it was reported that the number of PGY2 residencies is growing more rapidly than PGY1 residencies. Ambulatory care residencies continue to grow at the fastest rate.

Pharmacy Technician Stakeholders Consensus Conference Proceedings

The Council discussed published outcomes of the [Pharmacy Technician Stakeholders Consensus Conference](#), a national consensus conference that engaged all sectors of pharmacy in identifying points of agreement regarding entry-level requirements for pharmacy technicians. The increased availability of distance learning programs has changed the issue of access to technician education programs for remote locations without local programs. The Council continued support for the 2020 goal that 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.

Interprofessional Competencies

The Council discussed interprofessional education (IPE), which is widely recognized as members or students of two or more professions associated with health or social care, engaged in learning with, from, and about each other to enable effective collaboration and improve health outcomes. The recommendation from the ASHP House of Delegates was to determine whether there are policy gaps around interprofessional education in ASHP policy and residency competencies, including the interprofessional clinical learning environment. After review of existing ASHP policy and PGY1 and PGY2 competency area goals and objectives (CAGO) lists, Council members felt that ASHP policy and residency standards were heavily weighted toward interprofessional education. ASHP's upcoming participation in the [National Collaborative for Improving the Clinical Learning Environment](#) (NCICLE) Interprofessional Clinical Learning Environment Symposium, where the intent is to enhance a national conversation that seeks to identify ways to assist clinical learners to embrace interprofessional collaboration and learning was discussed.

2018 Report of the ASHP Treasurer

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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 2017 (prior year), (2) the projected performance for fiscal year 2018 (current year), and (3) the budget for the fiscal year 2019, ending May 31, 2019.

ASHP segregates its finances into two primary budgets, core operations and the program development and capital 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 and capital 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 and capital budget is funded primarily with investment income from reserves/net assets. Ad-

The Board of Directors, CEO, and staff of ASHP remain committed to supporting and advancing the profession of pharmacy.



ditional spending from reserves/net assets is only occasionally used to fund programs. Funding requests from reserves/net assets are reviewed on a case-by-case basis and approved by the Board of Directors. As a result of ASHP's sale of its previous headquarters building, there are two additional funding sources. The first is the building fund. The building fund was created to hold the net gain from the sale of ASHP's previous headquarters building so that the long-term investment earnings can be used to pay for lease and other occupancy-related expenses associated with ASHP's current headquarters office throughout the term of ASHP's lease. The second additional funding source is the building sale reserve funds. The building sale reserve funds were created with a portion of the cash proceeds from the sale of ASHP's previous headquarters 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. Funding requests from the building sale reserve funds are approved by the Board of Directors on a case-by-case basis.

The fiscal year 2017 financial audit of ASHP and its subsidiary, the 7272 Wisconsin Building Corp., for fiscal year 2017, ending May 31, 2017, was performed by the independent audit firm of Tate & Tryon. The audit result-

ed in ASHP receiving the best opinion available, an unmodified opinion.

Fiscal Year 2017 (Ending May 31, 2017)—Actual

ASHP's core operations had another successful year, with a \$219,000 surplus, and the program development and capital budget had a surplus of \$2.4 million due to better-than-budgeted investment income (Figure 1). Spending from reserves/net assets was \$312,000, and there was a favorable pension adjustment of \$43,000. ASHP's net assets at May 31, 2017, represented 80%¹ of total fiscal year 2017 expense. Our long-term financial policy is to maintain reserves/net assets at a target of 70% of total ASHP expenses.

ASHP's May 31, 2017, year-end balance sheet (Figure 2) remained impressive. The May 31, 2017, asset-to-liability ratio stood at 5.45:1.

Fiscal Year 2018 (Ending May 31, 2018)—Projected

As of February 28, 2018, the financial performance from core operations, the program development and capital budget, reserves/net assets, and building sale reserve funds for the fiscal year ending May 31, 2018, is projected to produce net income of approximately \$1.4 million (Figure 1). We anticipate the building fund will show a total accrual accounting deficit in the range of \$430,000 at fiscal year-

end. However, using the cash basis, we will have positive cash flow from the building fund. Projections do not include any potential pension adjustments.

Fiscal Year 2019 (Ending May 31, 2019)—Budgeted

ASHP’s fiscal year 2019 core operations, program development and capital budget, and building sale reserve funds budgets are balanced, with a combined \$1.2 million surplus (Figure 1). We are pleased to continue

to keep ASHP’s total dues revenue at a low 13% of total core revenue. We are also pleased to have surpassed 45,000 total members. Reserves/net assets expense is budgeted at \$405,000. ASHP’s total reserves/net assets are still budgeted to be at a strong 83% of total fiscal year 2019 expense.

With respect to the building fund, it is budgeted on the accrual basis at a slight deficit of \$184,000. On the cash basis, we anticipate the building fund will have positive net cash flow during fiscal year 2019.

7272 Wisconsin Building Corporation

ASHP’s subsidiary, the 7272 Wisconsin Building Corp., owned ASHP’s previous headquarters building in Bethesda, Maryland, and derived income from leased commercial and office space that was used to support ASHP’s expansive membership mission. This subsidiary is in the process of being closed down in an orderly manner.

The highly successful negotiations that resulted in the decision to sell our

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

	Actual Fiscal Year Ended 31-May-17	Projected Fiscal Year Ended 31-May-18	Budget Fiscal Year Ended 31-May-19
CORE OPERATIONS			
Gross revenue	\$48,843	\$50,651	\$52,585
Total expense	(48,774)	(49,544)	(52,732)
Investment income subsidy	150	150	150
Core Net Income	\$219	\$1,257	\$3
PROGRAM DEVELOPMENT AND CAPITAL BUDGET			
Investment income	\$3,437	\$1,377	\$1,555
Program revenue	156	467	330
Program and capital expenses	(1,168)	(1,583)	(1,058)
Program Development and Capital Budget Net Income	\$2,425	\$261	\$827
Programs Funded from Reserves/Net Assets	(\$312)	(\$742)	(\$405)
BUILDING SALE RESERVE FUNDS			
Investment income	\$75	\$810	\$846
Expenses	0	(175)	(25)
Building Sale Reserve Funds Net Income	\$75	\$635	\$821
Increase in Reserves/Net Assets	\$2,407	\$1,411	\$1,246
Pension plan adjustment	43	---	---
Net Increase in Reserves/Net Assets	\$2,450	\$1,411	\$1,246
BUILDING FUND			
Investment income	\$6,336	\$4,209	\$4,493
Building expenses	(3,662)	(4,639)	(4,677)
Building Fund Net Income	\$2,674	(\$430)	(\$184)

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

	Actual as of 31-May-17	Actual as of 31-May-16
ASSETS		
Current assets	\$5,596	\$5,449
Fixed assets	\$11,113	\$329
Long-term investments (at market)	\$38,085	\$34,497
Long-term investments (at market) Building Sale Reserve Funds	\$16,100	\$0
Long-term investments (at market) Building Fund	\$86,282	\$102,141
Investment in 7272 Wisconsin Building Corp.	\$199	\$5,642
Other assets	\$169	\$269
Total Assets	\$157,544	\$148,327
LIABILITIES		
Current liabilities	\$18,954	\$18,061
Long-term liabilities	\$9,945	\$6,746
Total Liabilities	\$28,899	\$24,807
RESERVES/NET ASSETS		
Net assets*	\$128,645	\$123,520
Total Net Assets	\$128,645	\$123,520
Total Liabilities and Net Assets	\$157,544	\$148,327

*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.

headquarters building have served our members extremely well and will continue to do so long into the future through the natural ups and downs in the U.S. and global economies. Most importantly, the sale has and will continue to allow ASHP to provide a growing list of highly valued membership services and the ability to advance the practice of pharmacy now and into the future.

Conclusion

It has been a pleasure to again

serve as your Treasurer this year. The Board of Directors, CEO, and staff of ASHP remain committed to supporting and advancing the profession of pharmacy. The financial strength of ASHP (solidified by the sale of the previous headquarters building) and diversity of ASHP's non-dues revenue sources allow for continued growth and development of a wide variety of additional member services, including educational resources, advocacy resources, and advancement of membership sections and forums.

It is truly an honor to be a part of this highly engaged membership organization that continues to advance the profession and positively impact pharmacy services to fulfill our Mission and Vision.

¹The building fund and the building sale reserve funds are excluded from the reserves/net assets calculation due to their designated use.

2018 REPORT OF THE PRESIDENT AND CHAIR OF THE BOARD

ASHP promotes resilience, pharmacy leadership, and technician training

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Keywords: forum, leadership, president, resilience, technician, well-being

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I encourage all of you to build upon the progress we have made this year by continuing to support our workforce and our frontline pharmacy staff.



It's hard to believe that my year as ASHP president is almost over. It has been a privilege to have the opportunity to serve you, ASHP, and the profession.

I would like to extend a heartfelt thanks to all of my colleagues and friends, both within and outside the pharmacy world, who supported me during this past year. Thank you to all of the administrators, pharmacists, residents, students, and technicians with whom I have collaborated, whom I've been inspired by, and from whom I learned during the past 12 months.

I also want to thank you, the members of the ASHP House of Delegates, for all that you do for the pharmacy profession, for patients, and for ASHP. The work of the House of Delegates, along with that of ASHP's councils, sections, forums, and state affiliates, shows your dedication to improving medication use, advancing patient care, and expanding pharmacist roles.

On behalf of the ASHP Board of Directors, I want to thank our chief executive officer, Paul Abramowitz, for his support and leadership throughout the year. His thoughtful guidance

and commitment to serving ASHP members and advancing the profession have made working with him a remarkable experience. Thank you, Paul.

The leadership element

In my inaugural address I talked about the importance of supporting our workforce and caring for our frontline pharmacy staff.¹ For pharmacists to help patients make the best use of medications, strong pharmacy leadership is important at all levels. Today I would like to share with you some of the many ways ASHP provides leadership and supports pharmacists and pharmacy technicians.

ASHP continues to spearhead efforts in providing guidance on the impact of rising drug prices. As a member of the steering committee of the Campaign for Sustainable Drug Pricing, ASHP has participated in numerous efforts to work collaboratively with our partners to address the issue of skyrocketing drug prices in the interest of ensuring that medications are affordable and accessible to those who need them. The group recently launched a major advertising campaign calling on Congress to pass the CREATES (Creating and Restoring Equal Access to Equivalent Samples) Act, a bill designed to reduce the price

and increase competitiveness of generic medications.²

In addition, ASHP reinforced our strong support for the 340B Drug Pricing Program before the Senate Committee on Health, Education, Labor and Pensions. Joseph Hill, director of ASHP's Government Relations Division, testified before the committee and emphasized that savings from the 340B program fund critical pharmacist-provided patient care services such as treatment for opioid misuse, medication management services, and management of chronic diseases.³

ASHP is also collaborating with the American Hospital Association and the Federation of American Hospitals on a survey for community hospitals and health systems to collect data on the impact of drug shortages.⁴ The survey results will be used in our collective advocacy efforts before policymakers and the public about the challenges of high and rising drug prices and drug shortages.

During my year as ASHP president, we witnessed some of the worst natural disasters in history—Hurricane Harvey, Hurricane Maria, and the wildfires in California. Hurricane Maria's impact on pharmaceutical manufacturing plants in Puerto Rico put 40 critical medications at risk for

being in short supply. ASHP supported members by providing up-to-date information for clinicians on our online Drug Shortages Resource Center. ASHP published numerous inspiring stories describing our members' heroic efforts to provide direct care to patients affected by these traumatic events.

As a leading healthcare organization, we have consistently advocated for strategies to manage and reduce drug shortages. For example, we hosted a drug shortage summit with other major organizations including the American Hospital Association, American Medical Association, Food and Drug Administration (FDA), and Institute for Safe Medication Practices to review and identify new opportunities to address ongoing supply-chain and patient care challenges associated with drug product shortages. A total of 11 specific recommendations, many involving proposed action by FDA or other federal entities, emerged from the meeting.⁵

A few months after Hurricane Maria, pharmacists faced another critical shortage, this time with small-volume parenterals or SVPs. In response, ASHP developed a fact sheet with the University of Utah Drug Information Service that outlined potential actions for healthcare organizations to consider when managing shortages of SVPs.⁶ ASHP, together with 5 other healthcare organizations, sent a letter to Congress urging it to take immediate action to address the public health crisis caused by shortages of SVPs.⁷ We also continue to work closely with FDA's Drug Shortages Program to assess the situation.

While clinicians scrambled to find medications that were in short supply, the opioid crisis in our country rose to new heights. Supporting our members while addressing the opioid crisis remains one of ASHP's highest priorities. At our headquarters in Bethesda, we hosted an interdisciplinary commission that included 22 top leaders from medicine, nursing, pharmacy, public health, regulatory agen-

cies, and academia to address this epidemic.⁸ The commission identified actionable solutions that would optimize pain management and defined pharmacists' leadership role on inter-professional teams.

ASHP also led national efforts to combat opioid abuse and misuse. We joined the National Quality Partners Opioid Stewardship Action Team and are partnering with other organizations to develop an opioid stewardship playbook to help healthcare providers manage their patients' pain while reducing the risk of opioid addiction.⁹ In addition, representatives from ASHP attended the White House opioid summit, where government agencies and advocacy groups gathered to address our nation's opioid crisis.¹⁰

When it comes to advocating for provider status, ASHP continues to pursue avenues that will give patients access to the services pharmacists provide. This includes not only national healthcare policy but also support for initiatives at the state level. We will keep you updated as these efforts continue to advance and evolve.

Supporting our workforce

In my inaugural address, I stated that it is up to us, as leaders in health-system pharmacy, to support our workforce by being their advocates.¹ I explained that it is critically important to develop and offer learning experiences to those around us. That same philosophy holds true for ASHP. We, as an organization, do a tremendous job of supporting our pharmacist, student, and pharmacy technician members.

This year we celebrated the 52nd Midyear Clinical Meeting in Orlando, which was also the culmination of ASHP's yearlong 75th anniversary celebration. During this meeting, we saw continued growth with the Residency Showcase, the Personnel Placement Service, and poster submissions. The Wednesday evening event at Universal Studios Orlando was the most well-attended event in the history of the Midyear Clinical Meeting, with well

over 10,000 attendees. For the third consecutive year, Trade Show News Network listed the Midyear Clinical Meeting on its list of the Top 250 Trade Shows of 2017.¹¹

Another way ASHP supports members and the pharmacy workforce is through residency education and training. In recent years, the number of pharmacy students participating in the residency Match has grown exponentially. Over the past 5 years, the number of postgraduate year 1 residency positions has increased by 35%, and the number of postgraduate year 2 residency positions has increased by 71%. This is an incredible accomplishment.

This is the third year that ASHP has offered a 2-phase Match program, which gives applicants who did not match during Phase I another opportunity to match with a residency program. Phase II of the Match resulted in 304 positions filled, in addition to the 3,831 positions filled during Phase I.

In 2017, ASHP launched 2 new professional certificate programs to help pharmacists and pharmacy technicians improve patient care. The Pain Management Certificate covers the optimal treatment of patients suffering from acute and chronic pain.¹² The other new professional certificate program, the Sterile Product Preparation Institutional Training Program Certificate, can be used as standalone education or in conjunction with other education and training at an institution.¹³

ASHP continues to support our 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. We recently launched 2 new review courses in cardiology and infectious diseases.¹⁴

ASHP's peer-reviewed journal, *AJHP*, keeps members up-to-date on the latest issues in health-system pharmacy. Last year, access to *AJHP* abstracts and articles exceeded 3 million, representing a 19% increase over the previous year. In addition to es-

establishing article collections on topics such as opioids, pharmacy technician roles, and drug expenditures, the journal published theme issues on population health management (September 15, 2017, issue) and optimizing medication use in multihospital health systems (April 1, 2018, issue). And, for the first time, *AJHP* published a list of its top 25 articles for the year.¹⁵

Technicians' roles

Many of you may remember from my inaugural address that I have a passion for developing the pharmacy technician workforce.¹ I believe that we need to help make pharmacy a career for technicians and develop their leadership capability. ASHP believes that, too. We launched the Pharmacy Technician Forum earlier this year. This new membership home within ASHP was created to advance the pharmacy technician workforce. It will serve as the central point for pharmacy technician engagement with ASHP, providing tools, education, and numerous other resources to help pharmacy technicians advance their practice. Another key focus of the forum is developing pharmacy technician leadership within ASHP, including participation in ASHP's policymaking process, strategic planning, advisory committees, and numerous current and evolving opportunities.

The Pharmacy Technician Forum recently selected its first executive committee, comprising 5 pharmacy technicians representing a broad spectrum of practice expertise, for the 2018–19 term. The committee held its first meeting here in Denver, where it identified the forum's mission, vision, goals, and objectives. The group also reviewed key issues facing technicians in order to identify professional and educational needs and tools and to advance practice.

The creation of the Pharmacy Technician Forum is not the only new development at ASHP. Another exciting new initiative is one that you may have heard about here at the Summer Meetings. Yesterday ASHP announced

the creation of a new Section of Specialty Pharmacy Practitioners. This new section will create an enhanced focus on ASHP's efforts to help its members provide optimal patient care and comprehensive medication therapy management in the specialty pharmacy environment in hospitals and health systems.

We are already working to appoint the new section executive committee, which will begin meeting this fall. Please be on the lookout later this month for a call for nominations, in case you or someone you know might be interested in serving on the inaugural executive committee. Membership and engagement in the new section will be available shortly thereafter to all ASHP members, including pharmacy technicians, residents, and students. More information will be sent out soon by ASHP about this exciting new section.

Resilience

Finally, I'd like to conclude by talking about another topic that is near and dear to my heart—resiliency and overcoming workplace burnout. A year ago, we announced ASHP's participation in the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience. Over the past 12 months, we assisted in the development of a conceptual model that shows the individual and external factors associated with clinician well-being and resilience.

In addition, we published a series of articles in *AJHP* focused on the well-being and resilience of pharmacy residents.¹⁶⁻¹⁸ We also launched a Clinician Well-Being and Resilience Connect Community. ASHP continues to work on this topic with our pharmacists, residents, student pharmacists, and pharmacy technicians by supporting research on risk factors for burnout and strategies to support resilience and well-being.

Conclusion

As my year as ASHP president

comes to a close, I encourage all of you to build upon the progress we have made this year by continuing to support our workforce and our frontline pharmacy staff. I have been incredibly fortunate to serve as your president, and I am deeply grateful to those of you gathered here in this room. ASHP continues to be a leading force in pharmacy today because of your time, tireless efforts, and dedication to the profession. During a year filled with rising drug costs, drug shortages, and an escalating opioid epidemic, our members trusted ASHP to provide them with education and resources so they could give their patients the best care possible. That is something we can all be proud of!

Disclosures

The author has declared no potential conflicts of interest.

Additional information

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2018 REPORT OF THE CHIEF EXECUTIVE OFFICER

ASHP: A powerful partnership of members, staff, and leadership focused on the unique value and expertise of pharmacists

Am J Health-Syst Pharm. 2018; 75:1247-50

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Keywords: disrupters, innovation, leadership, medication therapy experts, partnership, technician

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ASHP has worked and will work to establish the value of the pharmacist in serving patients not only on every hospital inpatient care unit but also in every ambulatory care clinic.



I would like to welcome and thank all of you as delegates for your time, dedication, and contributions to ASHP and our profession. The important work you do as highly engaged volunteers shapes ASHP's entire professional agenda and the work that ASHP does on your behalf. It is truly an honor and privilege to be here with you today.

Last year I spoke with you about ASHP's 75th anniversary and reviewed ASHP's accomplishments over the previous 5 years.¹ I also noted that the state of pharmacy practice and ASHP is strong, and the future is bright. Another year has passed, and our enthusiasm and excitement are even greater. Health-system pharmacy is, without question, heading in the right direction, and I hope you will agree with me that ASHP is leading the way!

The theme of my comments today is "ASHP: a powerful partnership of members, staff, and leadership focused on the unique value and expertise of pharmacists." The growing complexity and increasing impact of drug therapy on the prevention and management of disease demand a rec-

ognized medication specialist serving every healthcare team. This specialist is the pharmacist. ASHP has consistently sought over our now 76-year history to engage our members, staff, and volunteer leadership to accomplish this in multiple ways and would like you to know that ASHP absolutely will continue on this path.

Before I go further, I would like to take a few moments to recognize some very important individuals and groups. First, ASHP's exceptional staff of over 200 professionals who work tirelessly every day with unwavering commitment in support of our 45,000 members and the patients they serve. There is no better association staff team anywhere!

I would like to introduce 3 new members of ASHP's senior leadership team who began their work with us this past January. They are Lois Witkop, vice president and chief marketing officer; Bob Rosecrans, vice president and chief information officer; and Steve Rubloff, the new chief executive officer of our Foundation. I would also like to announce that Dan Cobaugh, currently our assistant vice president and *AJHP* Editor in Chief, has been promoted to vice president of ASHP Publishing.

Next, I would like to recognize the outstanding efforts of our president, Paul

Bush. Paul, you've been an inspiration and pleasure to work with and, of course, have done an awesome job in moving ASHP and the profession ahead.

Likewise, I would like to 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 serve all patient care teams. The board works incredibly hard to advance ASHP's membership, professional, and public health missions. I consider myself very fortunate to be 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 immensely to our profession and continue to do so.

Now back to the subject of my remarks. During these next few minutes, I hope to build on the theme "ASHP: a powerful partnership of members, staff, and leadership focused on the unique value and expertise of pharmacists" and share some thoughts on directions we might take to help bring us even closer to ASHP's vision that medication use will be optimal, safe, and effective for all people all of the time.

Achieving this bold vision implies that the pharmacist become health-care's medication therapy specialist. This will, of course, require ASHP to continue to promote continuous professional development for our members in multiple ways as outlined by Past President John Armitstead² in his inaugural address in 2015. It will require ASHP to further expand post-graduate residency training, development of board certification resources, certificate programs, and our vast array of in-person and digital educational programs and to promote credentialing and privileging processes in all health-system sites of care.

Let us not forget that, to successfully serve our patients, we will need an equally effective professional pharmacy technician workforce. This of course was one of the major underpinnings of President Paul Bush's³ inaugural address of 2017. Our vision is that all new pharmacy technicians will have completed an ASHP/Accreditation Council for Pharmacy Education–accredited technician training program before becoming certified and licensed and thus be prepared to take on additional responsibilities on our healthcare teams. The synergistic relationship between pharmacy technicians and pharmacists cannot be overstated.

We, therefore, are extremely pleased with the launch of the new ASHP Pharmacy Technician Forum. The goals of the forum are to create a significant and meaningful professional home for pharmacy technicians in ASHP and, most importantly, to elevate and advance the pharmacy technician workforce for the benefit of our patients and the overall advancement of pharmacy practice.

The response to the new forum by pharmacy technicians and pharmacists alike has exceeded expectations and is a clear sign that we are heading in the right direction. Further, the energy at ASHP headquarters and among our members about the new forum couldn't be greater!

I know we have already introduced Barbara Hintzen, our new chair of the

Pharmacy Technician Forum, but I would like to do so again. Barbara, this is a very significant moment in ASHP's history, and we are all pleased that you are here with us today. We look forward to many more technician leaders like yourself advancing the ASHP Technician Forum and thus the practice of pharmacy! Thank you for being an important part of this pioneering effort.

Now, a little about where ASHP is going next in the context of a rapidly changing healthcare landscape, starting with things that are already happening and moving to initiatives that might happen given the changes, innovations, and disruptions we are and will continue to experience in our healthcare systems.

My fundamental message today is that we as ASHP members need to continue to be our profession's pioneers, innovators, and drivers of change. The creativity, perseverance, and dedication of our members, staff, and leadership have been the key to our success. In the words of Clayton Christensen,⁴ we need to be disruptive innovators. Jim Casey, the founder of UPS, put it another way when he coined the term *constructive dissatisfaction*, which means that no matter how well we are performing, we can always transform and improve.⁵

The U.S. healthcare system has been undergoing both subtle and profound transformations. The federal government, through the Centers for Medicare and Medicaid Services and other payers, has made clear that the future of healthcare delivery and payment will not be based on the volume of services delivered, but rather on the quality, outcomes, and value delivered by the healthcare team.

Value-based payment models today require providers and healthcare organizations to meet a large array of quality measures, and many are either directly or indirectly medication related. Our members are leading efforts focused on optimizing medication therapy by preventing hospitalizations, reducing lengths of stay, effectively managing acute and chronic

disease in our clinics and ambulatory care pharmacies, enhancing wellness and disease prevention, “deprescribing,” and participating in many population health initiatives. We are doing so by applying the unique value and expertise of the pharmacist, providing comprehensive medication therapy management services that lead to measurable improvements in care and provide a significant reduction in healthcare costs.

Value-based healthcare has not only grown but will engulf how we provide care. So how does ASHP continue to help our members provide maximum value and, more importantly, anticipate and create our professional future? To illustrate how quickly things can change, we only need to look at Uber as an example of an idea that has transformed local transportation. The idea of connecting millions of individuals needing a ride with thousands of willing drivers through an app was such a profound idea but one that few ever saw coming.

As pharmacists, we cannot assume that changes will happen in familiar ways or follow current trends. Therefore, ASHP should attempt to anticipate, envision, and create new care models to maximize our value but which may be adapted to multiple scenarios of a future healthcare system.

Let's look at what is already occurring. We do know that we have value-based payment, continued growth of health systems, mergers of providers and payers, and the entry of once-thought-to-be-divergent companies into healthcare, like Amazon, Google, Apple, and Berkshire Hathaway, to mention just a few. We even have a consortium of hospitals now considering becoming a pharmaceutical manufacturer to confront the ongoing challenges with drug shortages and unsustainable increases in drug pricing.

Biotechnology in all forms is exploding, as are new developments in nanotechnology, pharmacogenomics, and a wide variety of healthcare apps and diagnostics. Technology is con-

necting us globally in new and unique ways every day, providing ASHP not only increased ways to learn from other parts of the world but business opportunities and new partnerships. Healthcare professionals are now often being trained in other countries using accreditation standards very similar to ours. These are just a few of the things we know, but what about the things we don't know?

ASHP has always looked to the future and has been the leader in creating new models of care and roles for the pharmacist. We began the Pharmacy Practice Model Initiative a decade ago, and it has now become the Practice Advancement Initiative, expanding to include ambulatory care. These initiatives have required us to firmly identify our unique value and define what our contributions are and should be so that we can adapt and provide the most value regardless of what form our healthcare system takes. I can assure you that ASHP will continue to follow on this path.

Simply stated, our unique value is that of being the medication therapy specialist, regardless of what form drug therapy takes in the future. The modalities may change, but the need for a specialist or expert who focuses on everything from basic to complex and personalized medication therapy needs will be our constant. Thus, everything ASHP can do to solidify and expand the health-system pharmacist in this role is essential. ASHP has worked and will work to establish the value of the pharmacist in serving patients not only on every hospital inpatient care unit but also in every ambulatory care clinic.

But, let's take things down from a 50,000-foot level and think about some fundamentals that ASHP is putting into place now to ensure we are leading and are prepared for the future. The first relates to my earlier mention of pharmacy technicians. Pharmacy technicians are as much if not more a part of our future growth and development as we are of theirs. Creating a technician workforce that

is appropriately trained, certified, and licensed and can safely and effectively take on an ever-increasing role in the medication-use process is essential. Our profession needs to reach consensus on the required education and training necessary for pharmacy technicians. As Past President Mick Hunt⁶ stated in his 2017 Whitney address, if the profession cannot come to consensus on this issue, ASHP should move ahead in our health systems.

Secondly, since most drug therapy is initiated, monitored, and changed in the ambulatory care setting, ASHP will continue to assist our members to move many more pharmacists into clinics and other health-system ambulatory care settings. However, we know that pharmacist access might not always happen in the way it does today. Therefore, should ASHP work with members to conceptualize groups of pharmacists who might be located in other sites using advanced technology, including virtual reality, to see patients and interact with the rest of the team, who may also be remote? In other words, should we be developing both structural models and digital models of care?

Please reflect on the example of Uber and how it changed transportation in our cities, and reimagine pharmacy care provided in a similar way. Could a digital platform connect pharmacists, patients, and other members of the interprofessional team, anywhere and anytime and in a way that is most convenient and efficient for the patient? Might we have pharmacist group practices in central locations that provide a wide array of services to patients, healthcare organizations, providers, and others? Of course this is not meant to, and should not replace, the in-person interaction between the pharmacist and the patient. However, not every hospital or clinic may be able to afford the optimal number of pharmacists onsite or have a pharmacy specialist in every discipline. This could be part of the solution to overcoming the very real challenges associated with availability

and cost. Along these lines, might we establish centers of excellence for innovation in pharmacy practice, where our best thinkers in health-system pharmacy can work together to develop and test new models of care?

Thirdly, it is time that credentialed and privileged pharmacists as medication therapy specialists take on much more prescribing authority in the context of the healthcare team. This is something that ASHP initiated with the development of collaborative drug therapy management spearheaded by Past President Jannet Carmichael⁷ in 1995. Should the credentialed and privileged health-system pharmacist become the primary prescriber of medications in his or her areas of expertise, and can we develop new care models to support this?

Finally, ASHP Past President Marianne Ivey⁸ led a movement a decade ago to elevate pharmacy directors in their organizations to chief pharmacy officers so that we could be at the table when important and far-reaching decisions are made. Might we now take the next step and work to place a pharmacy leader on the board of every healthcare organization? As Past President Roger Anderson⁹ stated in his 1987 inaugural address, "We should make no small plans."

After all, isn't innovation what we as ASHP members have been doing for 76 years? For example, we worked with and supported our members in establishing the formulary system, innovative drug distribution systems, clinical pharmacy services, pharmacy specialization, the role of pharmacists in clinics, advanced roles for pharmacy technicians, and many other practice enhancements. As Clayton Christensen might say, we have been pharmacy's disruptive innovators, and we should continue to do so. As Past President Lisa Gersema¹⁰ might say, pharmacy innovation should be our "true north."

These thoughts are just examples touching the surface of what is possible when ASHP fully unleashes its powerful partnership of members,

staff, and leaders to maximize our contributions to health and wellness. I recall that when Past President Cindy Brennan¹¹ asked in her 2006 inaugural address how can we all graduate to the next level, she answered with “By remembering that ASHP is here to help.”

I will end my comments by saying thank you. Thank you for being innovators and pioneers and for constantly demonstrating the unique value and expertise of pharmacy professionals. Thank you especially for everything you do for ASHP and your patients.

Disclosures

The author has declared no potential conflicts of interest.

Additional information

Presented at the ASHP Summer Meetings, Denver, CO, June 5, 2018.

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House of Delegates

NEW BUSINESS ITEM REFERRED BY 2018 ASHP HOUSE OF DELEGATES

*JUNE 4, 2018
DENVER, COLORADO*

NEW BUSINESS INTRODUCED BY (NAME):

Steve Riddle, Pharm.D., BCPS, FASHP; Diane Ginsburg (Past President); Pamela Stamm, Pharm.D., BCACP, BCPS, CDE; Mollie Scott, Pharm.D., BCACP, CPP, FASHP; Tricia Meyer, Pharm.D., M.S.; Judith Lovince; Jennifer Tryon, Pharm.D., M.S., FASHP; UT Delegation, WA Delegation

SUBJECT: The Pharmacist Role in Suicide Prevention

MOTION:

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

ASHP convene a broad-based task force of appropriate stakeholders to explore opportunities to enhance suicide awareness and prevention. Stakeholders to be considered are ASHP members, federal pharmacy personnel, state affiliates, colleges/schools of pharmacy, pharmacy professional organizations, pharmacy students, pharmacy residents and non-pharmacy entities. Areas for exploration should include the adoption of training models and tools for suicide screening, detection and intervention as well as the identification of methods for operationalizing suicide prevention strategies in various pharmacy practice and academic settings.

BACKGROUND

Suicide is the 10th leading cause of death in the U.S., and the number and rate of suicides are rising.¹ A recent study found that almost 40 percent of people have a healthcare visit within a week prior to their suicide attempt.² Healthcare professionals in all settings, including pharmacists, are in a unique position to notice depression and suicide warning signs in their patients and to intervene early. Unfortunately, healthcare professionals – and student learners, and practitioners in training – are also at a significant risk for suicide. Suicide is a preventable public health issue and understanding the stressors and hopelessness that lead people to consider suicide and connecting them to the appropriate help can save lives. Pharmacy professionals can play an important role in preventing suicide, overdoses and suicide attempts – creating safer homes, schools and work places. Unfortunately, these professionals and the organizations they work within are generally poorly prepared to address this critical issue

Issues related to suicide management are broad in scope and include assessment, detection of at-risk

individuals and proper subsequent management, as well as dealing with the impact of a completed suicide on family, friends, colleagues and coworkers. However, awareness of and identification of persons at risk for suicide along with appropriate referral has been a common first step in this process.

There are currently 9 states (CA, IN, KY, NV, NH, PA, TN, UT, WA) that mandate healthcare professionals (HCPs) undergo training in suicide assessment, treatment, and management.³ As an example of a coordinated effort to address such issues, Washington State launched a state-wide, comprehensive plan to prevent suicide-related deaths. The Washington Department of Health executed a policy mandating training for HCPs and, as of 2017, pharmacists have now been added to this required training list. Pharmacists must complete a one-time training in suicide assessment, treatment, and management. The training for pharmacists includes content related to the assessment of issues related to imminent harm via lethal means. The Washington State Pharmacy Association (WSPA) is now organizing such training for pharmacists.

Examining issues of suicide prevention from the ASHP perspective, the Society has recently focused policy and other organizational efforts on professional well-being and resilience, but no specific actions have been taken around the issue of suicide prevention. There are also no standards in place for the pharmacy residency programs with regard to wellness or the related issue of suicide risks.

SUGGESTED OUTCOMES

ASHP can serve as a catalyst to engage affiliates, members, pharmacy organizations, colleges and schools of pharmacy, and other stakeholders to explore best practice models and innovative ideas around the role of pharmacists (and HCPs) in suicide prevention and management. The spread of formal training programs and best practices would be a notable metric for success. Some other recommended outcomes are listed below:

1. Successful initiation of and recommendations from a task force of stakeholders that identify needs and develop strategies for suicide prevention including suicide risk evaluation and intervention training and tools.
2. Creation of residency accreditation standards that address wellness and resiliency and related suicide risks with consideration for education and training of residents, residency program directors and preceptors.
3. Delivery of education on suicide risk and prevention to members at ASHP conferences and other educational forums.

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House of Delegates

Recommendations from the 2018 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. Pharmacist-specific Issues in Parenteral Nutrition

Carol Rollins (AZ, MA)

Recommendation: Recommend that ASHP offer continuing education activities (e.g., boot-camp, plenary sessions, certificate program) that include patient care and pharmacist-specific issues (e.g., stability compatibility, calculations, storage) related to both adult and pediatric parenteral nutrition management.

Background: Many pharmacists, especially non-specialists, look to ASHP for continuing education related to parenteral nutrition (PN) as non-specialists are often being asked to manage the fluid and electrolyte portion of PN when a nutrition support specialist is no longer employed. Leaders in nutrition support pharmacy recognize a growing need for education related to pharmacy-specific information that often has a potentially profound effect on safety, especially as few colleges/schools of pharmacy and few residency programs now offer significant training in nutrition support, either adult or pediatric. Shortages have exacerbated issues of safety related to PN as product exchanges often carry compatibility and stability implications beyond those recognized by non-specialist pharmacist, and recent programming related to PN at ASHP meetings has primarily focused on ASPEN's recommendations for PN safety, not the pharmacist-specific issues. While a 70% overlap may exist in knowledge for interdisciplinary members managing PN, the pharmacist-specific information that has the potential for fatal outcomes is not "picked up" by any other profession and more pharmacist with minimal PN training are now performing PN management duties because training programs that help prepare pharmacists for this specialty role have become scarce.

2. Diversity and Inclusion

Christopher M. Scott (IN); Tate N. Trujillo (IN); IA, CT, PA, NH

Recommendation: Given the diversity of patients whom we serve, we recommend ASHP intentionally and strategically expand and support initiatives that promote diversity and inclusion in programming, policy, leadership, recognition, and membership. (This should incorporate all realms of diversity and inclusion, e.g., ethnic, cultural, gender, LGBTQ, etc.)

Background: Additional information available from contact.

3. Concern of Gray Market Distributors/Wholesalers

Lonnye Finneman (MT)

Recommendation: Council of Pharmacy Management revise existing ASHP drug distribution policy(s) to address the concern of gray market distributors/wholesalers contributing to increased drug prices and drug shortage issues.

Background: We have a nationwide issue with drug shortages and rising pharmaceutical costs. Gray market companies (such as Reliance Wholesale) are able to provide drug products even when primary wholesalers and manufacturers are unable to supply these products to customers, and therefore these drug products are not provided through normal distribution channels. These same gray market distributors/wholesalers have dramatically increased the cost of some of the drug they provide (i.e., dobutamine vial cost of \$99 per vial). Upon review of ASHP policy 1602 (Drug Product Supply Chain Integrity) and policy 1707 (Pharmaceutical Distribution Systems), this issue is not addressed. ASHP should have a firm stance on preventing these companies from contributing to the rising drug costs and drug shortages we are facing.

4. Multi-state Law Certification

Matthew Christie (ME)

Recommendation: ASHP work with states to develop regional licenses for pharmacists such as New England as done by other professions and VA.

Background: Additional information available from contact.

5. The Alignment of Beyond Use Dating for Single Dose and Multi-Dose Vials

Caryn Belisle (MA)

Recommendation: In order to reduce drug waste and mitigate safety risks in the event of drug shortages, all enforceable regulatory standards that address the beyond-use-date of a single or multi-dose drug vial must be in alignment with each other, and also recognize published literature that supports beyond-use-dating.

Background: With the impending draft revisions of USP <797>, the implementation of USP <800>, and the Joint Commission (JC) standards, there are misalignments with current practice standards as it pertains to drug shortages and reducing injectable vial waste. The JC has made it clear that the beyond use date (BUD) of a drug vial must not exceed that of what is recommended from the FDA approved package insert. This becomes a challenge when trying to mitigate risks during the drug shortage crisis, especially when USP <797> allows an extended BUD from a sterility standpoint. In addition, when studies in potency, stability, and sterility are completed at the local level or if there is actual published literature, it can become confusing as to what is or is not an acceptable BUD of a drug vial.

6. Student Learner Consistency within Policies and Position Statements

Section of Ambulatory Care Practitioners

Recommendation: The Section of Ambulatory Care Practitioners recommends that ASHP create an advisory group to review existing policies and position statements for alignment and the consistency of inclusion of student learners.

Background: In some ASHP policies and position statements, student learners are specifically called out, and in some, they are not. In some circumstances, it is appropriate to exclude student learners, however, a thorough review of existing policy would be helpful to ensure consistency.

7. USP 797: Literature-based Beyond Use Dating

Jeff Little (KS, MO)

Recommendation: ASHP should work with USP to develop evidence to support and potentially update USP 797 standard beyond use dating.

Background: USP 797 beyond-use dating leads to an incredible amount of wasted sterile preparations. The evidence to support the current beyond-use dating recommendations is lacking. ASHP could work with USP to develop evidence around beyond-use dating. This evidence could decrease waste in compounded sterile preparations and potentially even decrease the amount that health-systems spend on items from 503B compounding pharmacies.

8. Creation of a New PGY-1 Residency Program in Pharmacy Operations

Justin Konkol (WI and the Vizient Pharmacy Executive Committee)

Recommendation: We ask ASHP to create a task force to develop competency areas, goals, and objectives (CAGO) for the creation of a new PGY-1 health-system pharmacy operations residency program.

Background: There is an acute and significant need for pharmacists with specialized training to work in inpatient pharmacies, infusion centers, etc., that understand the operational components and complexities of this environment. Currently, there is not enough flexibility/time in PGY-1 pharmacy residencies to adequately train and develop the skillset needed to competently staff in these areas. There are a small number of PGY-2 programs in the market that focus on med use systems, but the graduates of these programs historically have been hired into administrative positions rather than staffing in the areas.

9. Technician Representation on ASHP Councils

Lindsay Massey (KS, MO, IL)

Recommendation: To recommend that ASHP evaluate the role of a technician representative on the ASHP Councils.

Background: With the newly formed ASHP Technician Forum, and the inclusion of student and new practitioner representatives, it may be of value to add a technician representative to certain councils.

10. Meeting Attendance Incentives for ASHP-related Positions

Section of Clinical Specialists and Scientists

Recommendation: Encourage ASHP to evaluate meeting related incentives to ASHP-related positions (e.g., program presenters, council chairs/vice chairs, section network facilitators, as appropriate) when meeting related activities are integral to the designated role.

Background: Understanding limited meeting monies, we ask ASHP to re-evaluate distribution of monies to members attending meetings to perform ASHP related duties such as those presenting programs, council chairs/vice chairs discussing policy rationales at the HOD and some section network facilitators who host networking sessions.

11. Delegate Financial Support for ASHP Annual Summer Meetings

Michelle Eby; Carla Darling; (Washington Metro Area)

Recommendation: We recommend that ASHP provide reduced or waived registration fees for each delegate to attend the ASHP Annual Summer Meetings.

Background: Regional delegates provide invaluable recommendations to ASHP, and this entails time, effort, and dedication. Local pharmacy societies work diligently to recruit experienced and knowledgeable pharmacists to represent their society but are unable to pay for the cost of travel to the Regional Delegate Conferences (RDC) and travel/registration to the ASHP Annual Summer Meetings for each delegate.

12. Social Determinants of Health

Davena Norris (NM)

Recommendation: To encourage the development of policy related to training pharmacists and student pharmacists to understand, identify, and address social determinants of health in collaboration with other team members.

Background: Social determinants of health (SDH) are the conditions under which people are born, grow, live, work, and age and the wider set of forces and systems shaping the conditions of daily life (WHO). SDH strongly influence health risk and outcomes. Thus, addressing SDH is important for improving health and reducing health disparities (Healthy People 2020). As pharmacists are increasingly integrated into healthcare teams, it is vital we become more knowledgeable about and develop skills for identifying and addressing SDH.

13. Collaborative Practice Consistency

Section of Ambulatory Care Practitioners

Recommendation: The Section of Ambulatory Care Practitioners recommends that ASHP convene a task force to review existing policies and position statements for consistency in use of the term collaborative practice.

Background: In 2017, the ASHP House of Delegates passed policy 1715 entitled Collaborative Practice. There was debate among delegates about the most appropriate term for this type of activity. Some ASHP policy position statements, such as policy 0905 refer to this activity as CDTM. The Section feels that a thorough review of existing policy for consistency of language would be helpful.

14. New Antimicrobial Therapy Advocacy

Lucas Schulz (WI)

Recommendation: To advocate for identification of innovative strategies to incentivize pharmaceutical manufacturers to continue developing and studying optimal use scenarios for novel antimicrobial agents and immune modulation therapies.

Background: Recent Congressional acts have encouraged industry to re-enter the antimicrobial R&D sphere; however, newly approved antimicrobials are met with restrictions and limited adoption into patient care due to very limited FDA approved indications. This slow uptake threatens the development pipeline. Therefore, ASHP should partner with industry to develop strategies to bring novel therapies and encourage use in clinical scenarios to market which do not place the health system financial well-being or patient care at risk.

15. USP 800: Ensuring Safe and Consistent Implementation

Jeff Little (KS, MO)

Recommendation: ASHP should work with USP to develop evidence based/expert opinion national standards for safe and consistent implementation of the USP 800 standard to prevent each institution from evaluating and developing their own standards.

Background: To promote safe, consistent, efficient, and cost-effective decisions, ASHP needs to provide leadership around the uncertainty with USP 800. The uncertainty will lead to institutions making their own decisions which will lead to variations in practice. One example is that ASHP should organize the literature review of NIOSGH Table 2 and Table 3 medications to standardize hazardous medication for a safe and consistent USP 800 implementation.

16. Recruitment of Pharmacy Technicians to Pharmacy Workforce

Lonnye Finneman (MT)

Recommendation: Recommend that the new Pharmacy Technician Forum develop and disseminate information related to career opportunities to enhance recruitment and retention of qualified pharmacy technicians.

Background: ASHP policy 1610 Career Opportunities for Pharmacy Technicians has a clause that states “To develop and disseminate information about career opportunities that enhances the recruitment and retention of qualified pharmacy technicians. In rural states, such as Montana, recruiting individuals to enter the workforce as a pharmacy technician is a challenge. So many career opportunities exist for pharmacy technicians and being a pharmacy technician can be a valuable and rewarding career. Many individuals have never heard about pharmacy technicians and the opportunities that exist, though. Therefore, there is a need to develop informational materials and bring national media attention to the need to recruit more qualified pharmacy technicians.

17. Outside Access to Health System Electronic Health Records for Transitions of Care

Dave Hager (WI)

Recommendation: That ASHP create a policy encouraging pharmacists in post-discharge care locations such as ALFs, SNFs, LTACs, and community pharmacies be granted health system electronic health record access to improve the safety of the transitions of care process with explicit oversight on who may obtain access by the health system's pharmacy department.

Background: Pharmacists must have access to patient data to make appropriate interventions during vulnerable transitions of care. Many health-system information systems departments make determinations on who may be granted external access the electronic health record without pharmacy department input. This policy would support the judicious expansion of EHR access to improve patient safety through transitions of care and establish the pharmacy department's role in evaluating the appropriateness of such requests.

18. Emergency Supply of Medications during Catastrophic Events

Charzetta James (FL)

Recommendation: To advocate for increased limits in day's supply of prescription medication dispensed by non-community pharmacy permit holders during catastrophic events.

Background: During Hurricane Irma many institutions were forced to keep higher patient census because of a lack of access to community pharmacies once discharged. Through the state of Florida patients were struggling to find pharmacies open to fill their prescriptions and were returned to the hospital. Currently only 72 hour supply is allowed. This recommendation advocates for up to 14 day supply to bridge the gap between the catastrophic event and service recovery in the community.

19. Recognition of Perpetual Inventory of Controlled Substances in Automated Dispensing Technologies

Kate McKinney (OH)

Recommendation: To encourage ASHP to partner with the DEA to recognize perpetual inventory of controlled substances (CII-V) for biennial inventory (title 21 CFR Part 1304.1) inventory requirements.

Background: ASHP's PAI encourages the use of automation and technology to support the expansion of the practice of pharmacy. Automated dispensing technologies are robustly utilized in the practice and delivery of health-system pharmacy. These technologies support pharmacy oversight to detect, deter, and decreased potential for drug diversion and support a closed loop chain of custody for disposition of drug. Following recommendations for and building upon the best practices described in the automation and technology section of the ASHP report ASHP Guidelines on Preventing Diversion of Controlled Substances. Recognition of perpetual inventory of ADTS is encouraged in place of biennial inventory required by the DEA.

20. Pharmacist Authority to Prescribe Controlled Substances

Heather Ourth (VA Affairs)

Recommendation: ASHP to develop policy and advocacy efforts to support state practice act expansion for prescribing of controlled substances by pharmacists, including federal authorization which allows pharmacists to obtain X waivers to prescribe medication assisted treatment.

Background: Currently 42 states prohibit the prescribing of controlled substances by pharmacists. This limits the pharmacist's ability to manage patients and fully integrate as providers in the areas of mental health, addiction, and pain management.

21. ASHP Policy to Manage PBMs (or Guidelines)

Nish Kasbekar (PA)

Recommendation: That ASHP develop strategies to assist health systems with managing PBM relationship or assisting health systems (providing guidance) to create their own.

Background: PBMs are unregulated and changing rules often. Hospital pharmacy departments are not always involved in PBM interactions. PBM have fees that could benefit pharmacy departments.

22. Sections and Forums Integration

Kevin Marvin (VT, MA, NE)

Recommendation: We recommend that ASHP develop a structure that manages issues identified by sections and forums that require integration of resources between the sections and forums to address specific topics and create specific deliverables. Furthermore, this structure should be supported by ASHP staff and have additional staff as specialized task forces are created.

Background: It is important that the appropriate specialists be involved in discussion and deliverables on issues impacting multiple sections. In addition, the work should be done in an integrated way to arrive at the best solution for all stakeholders.

23. House of Delegates State Affiliate Membership Requirement

Amada Hansen (OH)

Recommendation: Consider requiring state affiliate membership as a requirement of serving as a state representative for ASHP HOD.

Background: Active engagement with constituents within the state represented is imperative to effectively understand local practice dynamics. This is most efficiently achieved through state involvement.

24. Amazon Entry into Pharmacy

Section of Ambulatory Care Practitioners

Recommendation: The Section of Ambulatory Care Practitioners recommends that ASHP partner with other national pharmacy organizations to approach companies that are considering entry into the healthcare marketplace (i.e. Amazon) about being at the table for discussions that would affect the profession of pharmacy.

Background: There have been many conflicting reports about Amazon's entry into healthcare and the potential disruption of the pharmacy profession. There is confusion and tension among ASHP members regarding what could happen if Amazon enters the pharmacy market. Will prescriptions be orderable through Alexa and sent to patients' doors? Will community pharmacies become obsolete? As there is no clear idea of what may occur, it is difficult to prepare for the potential disruption. It is critical that ASHP is at the table with companies such as Amazon to serve as an important player in the decisions that get made, guide/influence the direction that Amazon takes, and/or at a minimum be responsible for informing members on strategy for how best to prepare.

25. Addressing Barriers to Biosimilar Reimbursement

Karen McConnell (CO); Amy Sipe (MO); Snehal Bhatt (MA)

Recommendation: For ASHP to evaluate the impact of reference product rebates on the third party reimbursement of biosimilar products.

Background: The adoption of biosimilars has been stymied due to rebate programs offered and paid by the pharmaceutical manufacturers of reference products (e.g., Remicade). These rebate programs, paid not only to providers, but also to third party payers (e.g., insurance), incentivize third party payers to not cover biosimilars. This results in biosimilar products not being available to many American patients. In order to support the availability and success of biosimilars in the US to foster competition, ASHP should oppose these rebate programs.

26. Disclosure of Price Increases by Drug Product Manufacturers

Jesse Hogue (MI)

Recommendation: ASHP should develop a policy to advocate that drug product manufacturers be required to provide public notification in advance of significant price increases.

Background: The Formulary and Pharmacy & Therapeutics Policy and Guideline Advisory Panel suggested such an amendment to ASHP policy 0814, recognizing the challenges presented by recent exorbitant drug price increases. Requiring early notification would enable health systems to proactively manage shortages and their budgets. These price increases are often passed on to patients out of necessity, which can then adversely impact patient access to those medications and therefore worsen patient outcomes.

27. Professional Organization Involvement/Engagement as a Professional Obligation

Katie Morneau (TX, NH)

Recommendation: Professional organization involvement is a professional responsibility and no current ASHP policies exist that speak to this topic.

Background: Other professional organizations have literature supporting value of membership in professional organizations (pharmacists do not). Value widely accepted by individuals but not necessarily workplaces and SOPs support from employers and SOPs vary widely and do not often reflect the value of service.

28. Availability of Electrical Outlets at House of Delegates

Carla Darling and Laura Zendel (Washington Metro Area)

Recommendation: Consider providing necessary resources for HOD meeting such as electrical outlets.

Background: In the era of growing electronic devices necessary to review, research, assess, and evaluate information, it would facilitate the work of delegates during the HOD meetings.

29. Cannabinoids

Scott Anderson (VA)

Recommendation: Recommend ASHP to review and update policy 1101 to include cannabinoids and related research.

Background: Additional research exists that was not available when the policy was created in 2011, as do additional cannabinoid products. State laws are being created as a result. ASHP should review their existing policy to include additional products and update the vocabulary with the correct terminology.

30. House of Delegates Term Limits

Scott Knoer (OH)

Recommendation: Consider imposing term limits on ASHP state delegates to give more members the opportunity to be involved and engaged.

Background: Being an ASHP delegate is a great way to get involved. Many leaders got their start as delegates. By imposing term limits more pharmacists can take part in this important process.

31. Pharmacist Involvement in Post-Acute Care Settings

Tammy Cohen (TX)

Recommendation: That ASHP recognize that post-acute care pharmacy services are integral components.

Background: A majority of hospitals in the U.S. are small and medium bed size. The request of ASHP is to include this group of facilities in future ASHP forecast publications (e.g., SNIF, LTAC).

32. Student Programming: Resilience

Nancy Korman (CA)

Recommendation: ASHP to develop programming specific for the student forum that addresses student specific scenarios which lead to burnout and stress.

Background: Today's pharmacy student feels the need to strive for perfection in many areas (academic, placement in the best pharmacy practice experiences, a CV replete with multiple leadership positions, community service activities, and research). In addition after graduation, they face the economic reality of a substantial debt from student loans. Their stress level is high, and they lack the tools to cope and be resilient. Programming focused on resilience and recognizing depression and suicidality in themselves and peers would be helpful.

33. Utilization of Electronic Resources to Streamline Amendments, Recommendations, and New Business Items during the ASHP House of Delegates

Mindy Burnworth, Carol Rollins, Renee Tyree (AZ)

Recommendation: To recommend that ASHP investigate alternative electronic methods to collate recommendations, amendments, new business items, and other HOD relevant materials to streamline efforts and facilitate timely dissemination of revised information.

Background: The ASHP House of Delegates has implemented several electronic modalities to enhance policy deliberation (such as ASHP Connect, housing of delegate materials on the ASHP website, streamlined electronic communications, audience response system voting), many of these being supported by ASHP staff. To further advance and streamline efforts, it would be valuable to utilize an open communication system or electronic database that could automatically convert amending language (that already includes strike-through, underlines) from ASHP Connect to the official ASHP Amending Language forms and other forms, thus, preventing duplicative work. This will allow for more timely policy deliberations and streamlined ASHP staff workload.

34. Awareness and Education for Rare (Orphan) Diseases

Mindy Burnworth, Carol Rollins, Renee Tyree (AZ)

Recommendation: To recommend that ASHP develop a statement on the pharmacist's role in the management of patients with rare (orphan) diseases and orphan drug products; further,

To develop a resource center on rare diseases that includes information on orphan drug products (e.g., unusual procurement procedures, special handling, dosing and administration) and related disease information; further,

To collaborate with rare disease, medical, and other pharmacy organizations to promote healthcare provider and public awareness, education, and resources for patients with rare disorders.

Background: Unfortunately, many healthcare practitioners do not receive formal training or education on rare diseases and orphan drugs in recognized healthcare educational programs. Thus, general knowledge of rare diseases and orphan drugs is inadequate, forcing "reactive" on-the-job self-teaching. The promotion of increased awareness of rare diseases and treatments by proactively sharing facts and resources to assist in the care of a patient with a rare disease will bridge the rare knowledge gap. Collaboration with other healthcare professions and organizations including the National Organization for Rare Disorders, the Canadian Organization for Rare Disorders, Rare Diseases Europe, the Office of Rare Diseases Research Genetic and Rare Diseases Information Center, and Orpha.net will also narrow the gap, especially in light of advances in precision medicine. This will complement the policy on "Ensuring Effectiveness, Safety, and Access to Orphan Drug Products," COT 1.

35. Sterile and Non-Sterile Compounding Continuing Education

Section of Ambulatory Care Practitioners, Home Infusion Section Advisory Group, MA, AZ

Recommendation: Recommend that ASHP include a tract with multiple activities related to sterile and non-sterile compounding for the Summer 2019 Meeting, and then continue to provide compounding-related CE activities especially sterile compounding, in small units (e.g., 1-4 hours) through various formats (e.g., Midyear meeting, electronic formats) to meet the growing need for education in compounding.

Background: Some states, including Massachusetts, now require pharmacists to obtain CE in compounding, both sterile and non-sterile, and other states are considering this requirement. The BPS specialty in sterile compounding will increase the need for this type of CE. ASHP's current resources in sterile compounding are great initial training tools; however, they are relatively large modules that will not meet the need for ongoing CE where this is now required for license renewal. Implementation of this recommendation will likely improve attendance at the ASHP Summer 2019 meeting in Boston (Massachusetts requires sterile and non-sterile compounding CE for license renewal) and continued provision of CE in sterile compounding would help keep ASHP as the leader for those needing ongoing education in sterile and non-sterile compounding.

36. Use of International Classification of Disease Terminology in Publications

Paul Driver (ID)

Recommendation: AJHP and ASHP should use International Classification of Disease (ICD) diagnosis code terminology in publications.

Background: Provider status for pharmacists is inevitable. Once this occurs, the use of ICD language will be essential to prevent denials and obtain reimbursements. In order to make this change as seamless as possible, it is important that the correct language be incorporated into documentation and communications. The use of ICD codes in publications will allow all readers and authors to incorporate language consistent with the current coding and be compliant with the reimbursement system.

37. Reconsideration of Policy Title “Use of International System of Units for Patient and Medication-related Measurements”

Elizabeth Wade (NH)

Recommendation: I recommend amending the title of the policy to include medication-related measurements.

Background: Amendments were approved at this 2018 session of the House of Delegates to incorporate medication-related measurements into the body of the policy. The title should reflect the changes.

38. ASHP Guidelines for Pharmacist Relations with Industry

Jim Lile (MI)

Recommendation: That ASHP complete the update to ASHP Guidelines for Pharmacists’ Relations with Industry

Background: The existing ASHP guideline has remained unchanged for 25 years. The guideline was last reviewed by the Council on Pharmacy Practice in 2009. The Council found the document in need of updating. Nearly nine years have passed since that recommendation. A request for an update on the status of this guideline was submitted to the HOD in 2017 and the guidelines were posted for public comment in September 2017 with a goal of completing drafting by year’s end. We request a subsequent update.

39. Pharmacy Technician Forum Request

Steven Gray (CA)

Recommendation: Ask the Pharmacy Technician Forum to consider the ASHP policy that was just adopted regarding Student Pharmacist Drug Testing to apply to student and employed pharmacy technicians for adoption next year.

Background: The California Board of Pharmacy has identified that drug abusing and diverting persons are enrolling in pharmacy technician training programs to get access to drugs during experiential training and after during employment. Further that drug abusing students and employees are more likely to abuse and divert drugs. Further, such persons are being recruited by gangs and organized crime to enroll in pharmacy technician training programs to become pharmacy technician employees.

40. Recruitment Process: ASHP Residency Showcase

Joan Kramer (KS, MO)

Recommendation: To recommend that ASHP convene a task force to assess the ASHP Residency Showcase and resident recruitment process, including but not limited to match rates and residency program return on investment for participation; further, to recommend the task force findings and action plan to close any identified gaps be presented to the ASHP Board of Directors within the next 12 months.

Background: The ASHP Residency Showcase has existed in its current format for more than a decade. There is sparse data demonstrating the current resident recruitment process ensures a strong candidate pool or successful match rate for residency programs. Additionally, the return on investment for residency program participation at the showcase is unknown. Twenty-first century recruitment updates, such as additional technology resources, are needed to attract the best candidates and sustain residency program participation.

41. Incorporation of Sterile and Non-sterile Compounding Educational Sessions at the 2019 ASHP Summer Meetings

Karl Gumpper (MA)

Recommendation: ASHP should provide educational sessions at the 2019 ASHP Summer Meetings that provide both sterile and non-sterile compounding to meet MA pharmacist annual CE requirements.

Background: The site of the 2019 ASHP Annual Meetings (Boston) is located in a state whose pharmacists involved in compounding (either directly or supervising) are required to obtain a minimum of 5 hours on sterile compounding and 3 hours in non-sterile compounding on an annual basis. In addition to attracting ASHP members, such sessions would attract non-ASHP members and provide additional revenue to ASHP. Additional interest in compounding topics would also be driven with the anticipated official date of adoption of USP 795 and USP 797 in December 2019. Sessions should include practical hands on materials as well as regulatory updates that would appeal to both inpatient practitioners as well as those involved in home care.

ASHP Board of Directors, 2018–2019

Am J Health-Syst Pharm. 2018; 75:e568



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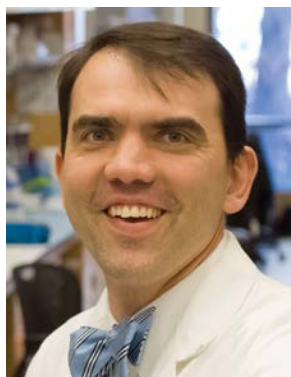
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Our pharmacy profession: Are you all in?

Am J Health-Syst Pharm. 2018; 75:1239-42

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Keywords: collaboration, connectivity, inclusivity, pharmacy technicians

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This moment and, more importantly, this opportunity to serve *you*—ASHP and the profession of pharmacy—have me feeling on top of the world!

One of the first actions that I took as I planned for this message was selecting a walk-in song. For mine, I chose “On Top of the World” by Imagine Dragons. The lyrics from this song truly capture so many of my emotions and perhaps yours as well. There have been times in my career when I felt like I fell flat, but I have always managed to get back up. When Imagine Dragons sing about paying dues, I empathize. I have been literally and figuratively paying my dues throughout my career—including my ASHP dues every year! Most importantly, I have been waiting for this moment, the moment to stand before you, for a while now, and yes, it’s as exciting as I had hoped!

I must admit, though, that I have not dreamed of this moment since childhood. I don’t even remember how I answered the question, “What do you want to be when you grow up?” I am certain that being a pharmacist and being elected president of ASHP were not on my list of career aspirations.

We must seize this opportunity to be all in—work on multidisciplinary teams, provide chronic care management, and collaborate with physicians, nurses, and community pharmacists to provide comprehensive care to patients as they move between settings.



In fact, to be perfectly honest, I happened upon pharmacy as a career in high school. A professor from a nearby college told me that pharmacists are problem solvers, they help people, and they make a difference in peoples’ lives. Those 3 qualities resonated with me. By the time I was in pharmacy school, I was “all in” for pharmacy.

As a student aspiring to become a drug information pharmacist, I connected with ASHP on the advice of several faculty members. They told me that ASHP and specifically the Mid-year Clinical Meeting were the places for me to find a residency program. I quickly learned that ASHP was about so much more than residencies. As a young drug information pharmacist, I discovered that ASHP was the organization that provided best practices for hospitals and health-system pharmacy and the gold standard in drug compendia. ASHP offered the first opportunity for me to interact with fellow drug information pharmacists in what were then called specialty interest groups. ASHP provided tremendous guidance and support to me as a young and eager residency program director. ASHP provided a venue for my first poster presentation, and *AJHP* was the journal that published my residency project manuscript. Over the

years, my career has taken me from drug information practice, to residency program leadership, to academia, to academic leadership. Through it all, I have always felt connected to and included in ASHP.

I found that being included in ASHP didn’t mean I had to practice in a certain area or have special credentials. This feeling of connectedness came from being valued for my unique perspectives. Reflecting on that now, I realize that connectivity is something that I highly value. It’s something that has made me an effective pharmacist and a better person. By being connected, I have provided better care and have supported others, regardless of differences in backgrounds and beliefs. Connectivity has helped me in my academic role too, where I shape young professionals and prepare them to care for a diverse patient population.

My message to you today is built on this construct of connectedness—the idea of being all in. Is there any better example of being all in than the football team in the TV series “Friday Night Lights?” Remember the mantra “clear eyes, full hearts, can’t lose?” They were all in. Collaborating, sharing, supporting one another, and working together. The same goes for us.

All in means working toward a common outcome but having a healthy respect for others even when their opinions differ from ours. *All in* is being fully committed to a purpose that unifies us.

Are we as individuals all in for our patients and the profession? Is ASHP as an organization all in to support you and your commitment to elevating the quality and safety of care that all patients deserve? I hope that I don't have to convince you that the answer to both questions is yes. Instead, I hope to affirm what you already know—that we're all in this together: pharmacists, student pharmacists, pharmacy technicians, residents, our healthcare colleagues, and, most certainly, our patients.

Connections

Today, we hear a lot about technology and how it can connect us. I can easily use my smartphone to conduct a video call with my mother, who happens to be sitting in the front row—Hi, mom! Even when we are hundreds of miles from each other, we can still connect through this easily accessible handheld device.

Pharmacists use similar technology to make connections, too, and not just with their families. Pharmacists can connect with remote hospitals to verify medication orders or to observe the actions of a technician preparing a sterile product. Technology allows us to shrink the world around us. As a result, we can provide patient care that otherwise may be impractical at a 16-bed critical access hospital in North Dakota or provide education for a student in rural Appalachia who is enrolled in an online pharmacy technician training program because the nearest program is more than 150 miles away.

This ability to be instantly connected is 1 of many technological changes happening in healthcare. Think about the shifts we experience now, including how the increased influence of pharmacogenomics, analytics, and artificial intelligence has

changed how we practice pharmacy. Drug therapy is built on the unique characteristics of the patient, rather than a one-size-fits-all approach. Artificial intelligence guides care decisions. We see enhanced diagnostic accuracy of melanoma and tuberculosis and have the ability to stratify patients on hospital admission for the development of sepsis. The combination of remote patient monitoring and clinical decision rules can likely prevent a recently discharged patient with heart failure from being readmitted.

But technology cannot do it all. People are people, and they respond best when they're treated as individuals. That patient who was discharged after a heart failure exacerbation has unique characteristics that cannot be fully supported by an algorithm. What if she has to travel 20 minutes on a city bus to reach a community pharmacy where she feels comfortable because it's the only pharmacy she knows about that routinely employs a Spanish-speaking pharmacist who she can talk to? And what if, the day before she needs a medication refill, the city bus breaks down, and she would rather wait until she can see that nice pharmacist who she can understand instead of visiting a closer pharmacy, or she doesn't even realize that she could request that her prescription be transferred to a pharmacy closer to her? Because of her life circumstances, this patient may not get the medications she needs and may soon return to the hospital for another heart failure exacerbation.

A human connection before her discharge could have easily changed her experience. The pharmacy resident on the cardiology team could educate the patient about her discharge medication regimen and connect her to a nearby community pharmacy that includes a Spanish-speaking pharmacist.

Here is another example of the value of human connections. What if you're coaching a Native American patient newly diagnosed with diabetes? You have to move beyond medication

therapy instructions to find out what is important to the patient. Forming a connection allows you to prescribe a healthy eating plan that recognizes his heritage (if that is important to him), to find exercise opportunities that fit his beliefs and align with his values, and to understand any challenges he may face when it comes to taking medications and making lifestyle changes.

What is the lesson here? All patients are unique, and their response to treatment is not defined solely by their genetic profile, laboratory findings, or DRG (diagnosis-related group) code. Recognizing that patients may have different socioeconomic characteristics or belief systems is 1 of many elements we must consider as we provide care and work to improve care networks.

Another important lesson is that, because of our expertise in disease management and patient communication, along with our accessibility and ability to connect patients to community and financial resources, no profession is better positioned to support the physical, mental, and social health of the population than pharmacy. We are the medication-use experts!

Pharmacists today are educated and trained in each of those 3 dimensions. Pharmacists are now serving as health coaches, healthcare system navigators, and accountability partners, all of which require collaboration and inclusivity within the healthcare system. We must seize this opportunity to be all in—work on multidisciplinary teams, provide chronic care management, and collaborate with physicians, nurses, and community pharmacists to provide comprehensive care to patients as they move between settings.

Caring requires connecting with others and being intentional and inclusive in the processes we develop. We must make sure we continue to connect with people, whether we are pharmacists, pharmacy technicians, public policy analysts, or pharmacy educators. When we go all in to con-

nect, we all benefit. And by *all* I mean patients, the care team, the hospital, and, of course, the pharmacy profession.

ASHP connections

Connecting with colleagues, both past and present and even future potential colleagues, is a tremendous benefit of attending ASHP's meetings. So, I ask you, have you gone all in to connect during the ASHP Summer Meetings? Have you truly connected with your colleagues and opportunities here in Denver? For many, the answer to this question is a resounding yes! For others, the thought of connecting with strangers doesn't come easily. I'm with you on that.

I am an introvert, and I've had to learn how to effectively engage and connect with people at meetings like this. It was difficult at first, but it became easier when I moved from approaching it as networking and truly tried to connect on a genuine level with others. My perspectives broadened, I started to feel more included in a variety of ASHP sectors, and my ASHP leadership journey began.

You all have the same tremendous opportunity—to make connections right here, right now, at the Summer Meetings. Be intentional about connecting with others. Keep making connections. I promise it will get easier!

ASHP initiatives

ASHP continues to go all in to support members like you as you care for individuals and patient populations. Our longstanding Practice Advancement Initiative, or PAI, has resulted in a great partnership with ASHP state affiliates to help drive practice change at the local level. To date, we have awarded 24 PAI State Affiliate Workshop grants, and PAI continues to provide practice tools and resources to drive foundational strategic planning with measurable results.

ASHP recently developed 2 new professional certificate programs—pain management and sterile product preparation—to help members attain

the necessary credentials to advance their practices.

And the Pharmacy Technician Forum is an exciting new way for technicians to feel connected to ASHP. This new membership home within ASHP was created to further elevate the pharmacy technician workforce while advancing pharmacy practice. To enhance that feeling of inclusion, we have also established new member benefits for technicians, including a reduced member rate and special technician-focused resources on the ASHP website, including articles published in *AJHP*. I had the good fortune to meet with the inaugural members of the forum's executive committee on Friday, and I assure you there will be some great work coming from that group.

ASHP continues to partner with the Accreditation Council for Pharmacy Education to accredit technician training programs through the work of the Pharmacy Technician Accreditation Commission. I have had the honor of working with that group, and I'm pleased to report it will soon implement a new standard to further strengthen the training provided to our aspiring technician colleagues. When we connect technicians to specialized training and include them in ASHP's policymaking processes, strategic planning, and advisory committees, we recognize the important role they play in healthcare.

ASHP is committed to ensuring the health of our greatest resource—our members. We recognize that the pace of healthcare, combined with daily stresses, can lead to employee burnout. My predecessor Paul Bush¹ talked about enhancing resilience and reducing burnout in his own inaugural address a year ago. Riding high on that wave, ASHP is the only pharmacy organization to be part of the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience. As a member of the collaborative, we helped develop a model that identifies factors associated with clinician well-being and resilience.

The Women in Pharmacy Leadership initiative that ASHP launched a few years ago continues to ensure that members are being included and that their voices are being heard. When it was first announced, this initiative sparked conversations about whether it was something our members truly needed. Those conversations were precursors to developments across our nation and around the world. Since ASHP launched the Women in Pharmacy Leadership initiative, other professional organizations have followed ASHP's lead and developed similar programs.

As a woman, but more importantly as a member of ASHP, I am proud that, once again, our organization is leading the pack on these critical professional and social issues. This also includes some great work from ASHP, which provided guidance to support LGBTQ members through publishing a recent article in *AJHP*² and hosting receptions at ASHP meetings.

These are just a few of the many examples of the efforts that ASHP has made to provide a professional home to pharmacists and pharmacy technicians. But there is so much more to be done to ensure that we are truly supporting, connecting, and including all of our pharmacy colleagues. I challenge each of you to ensure we are doing our best, and doing the right thing, for all of our current and potential members. If we are to be on top of the world, then we must be all in.

Conclusion

Supporting, connecting, including—these concepts underlie why each of us should be all in for pharmacy. They reflect the feelings we have for ASHP, our professional home that supports our own needs and those of our patients and connects us with those who can help us grow in our careers.

Remember that pharmacy professor who first connected me to pharmacy, and those faculty members who encouraged me to get involved in ASHP? Those very people are going to become my colleagues, as I will soon

become the first female dean of the University of Georgia College of Pharmacy. I can assure you that new role has me on top of the world!

My presence on this stage and my new role as a dean are the results of the roles that many of *you* have played in my life, my career, and my journey through ASHP. You were all in for me.

It all starts with my parents, Janice and Kenneth Smith of Statesboro, Georgia. Many of you in the audience will recognize my mother, as she is my number 1 traveling buddy, while my dad likes to stay close to home. Both she and my dad truly deserve the spotlight today. They have been my staunchest supporters and provided me with clarity of vision. Most importantly, they have always kept my heart full. Thank you for showing me the power of connections and for being all in for me.

In addition to my parents, there are scores of others who have been all

in for me. You reached out to me, encouraged me, pushed me, connected me, and made me feel included and welcome in this profession and this organization.

Each of us in this room has benefited from someone who has supported, connected, and included us. If you have benefited from someone who has supported, connected, and included you, please stand. Your list of connectors may be even longer than mine. Now, will you commit to connecting others? Will you be all in? If you're up for the challenge, then pull out your phones, turn on the flashlight, and hold them high. Hold them high! Now look around and remember this moment when you committed to being all in for your patients, all in for ASHP, and all in for the profession of pharmacy!

Thank you for your dedication to your patients and to pharmacy, and thank you for being a member of

ASHP. Now go all in for the Summer Meetings! With clear eyes and full hearts, we can't lose!

Disclosures

The author has declared no potential conflicts of interest.

Additional information

Presented at the ASHP Summer Meetings, Denver, CO, June 5, 2018.

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House of Delegates

REPORT ON IMPLEMENTATION OF 2017 ASHP HOUSE OF DELEGATES ACTIONS AND RECOMMENDATIONS

Council on Pharmacy Management 1701: Ensuring Patient Safety and Data Integrity During Cyber-attacks

To advocate that healthcare organizations include pharmacists in (1) assessing cyber-security systems and procedures for vulnerabilities, (2) implementing cyber-security strategies, 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.

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 1702: Reduction of Unused Prescription Drug Products

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.

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 1703: Pharmacist's Leadership Role in Anticoagulation Therapy Management

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.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

Board of Directors 1704: 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.

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 1705: 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.

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 1706: 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.

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 1707: 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 oppose manufacturers, distributors, and wholesalers making availability of drug products contingent on how those products are used.

This policy supersedes ASHP policy 1016.

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 1708: Mobile Health Tools, Clinical Apps, and Associated Devices

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.

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 1709: Controlled Substance 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 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.

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 1710: 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 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.

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 1711: 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, pharmacies repack 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.

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 1712: 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 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.

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 1713: Partial Filling of Schedule II Prescriptions

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.

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 1714: 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.

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 1715: Collaborative Practice

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 allow 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.

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 1716: Greater Competition Among Generic and Biosimilar Manufacturers

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

This policy supersedes ASHP policy 0222.

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 1717: 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.

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 1718: 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 electronic health records.

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 1719: 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.

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 1720: Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics

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.

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 1721: Clinical Significance of Accurate and Timely Height and Weight Measurements

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.

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 1722: 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.

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 1723: 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.

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 1724: 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.

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 1725: 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.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

USP 800 Assessment of Risk Standardization (Recommendation): Joan Kramer (KS), Richard Pacitti (PA), Christine Roussel (PA), Gregory Burger, Jesse Hogue

Recommend 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.

ASHP has several guidance documents (Handling Hazardous Drugs, Drug Distribution and Control: Preparation and Handling) and position statements (1615-Protecting workers from exposure to hazardous drugs) that urge careful consideration and handling of hazardous medications. In addition, NIOSH still uses the definition of a hazardous drug that was developed by ASHP in 1990. Your recommendation is consistent with our level of commitment to ensure patient and healthcare personnel safety regarding the handling of hazardous medications. We recognize your recommendation as an additional approach to consider as a way to support members.

Medical Surveillance of Healthcare Workers Occupationally Exposed to Hazardous Drugs on a Federal Level (Recommendation): 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.

ASHP agrees that it is important to continue efforts to minimize adverse health effects in personnel potentially exposed to hazardous drugs. In regard to your recommendation for medical surveillance, ASHP will join the [Center for Drug Safety at the University of Maryland](#) which has a strategic goal to develop and assess new methods for monitoring.

Guidance for Compounding Sterile Preparations in Short Supply (Recommendation): 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.

The Council on Pharmacy Practice discussed this topic during Policy Week and drafted the following policy recommendation which will be considered by the House of Delegates at its June 2018 meeting in Denver.

Availability and Use of Appropriate Vial Sizes (Voted 3)

VOTED TO RECOMMEND 3

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste (e.g., multiple-dose vials or single-dose vials of differing doses); further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the appropriate use of single-dose, single-use, and multiple-dose vials.

ASHP Guidance on Long-term Stability (Recommendation): 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.

This issue will be explored by the 2017-2018 Section of Ambulatory Practitioners Advisory Group on Home Infusion.

Pharmacist's Role in Sleep Management (Recommendation): 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.

The Council on Pharmacy Practice will be reviewing and discussing this topic before the next June House in 2018. The topic is relevant to our profession and patients. There may also be an opportunity to develop a

best practices guideline on this topic.

Pharmacist Oversight of Medication Records (Recommendation): Sylvia Belford (SOPIT)

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

The Council on Pharmacy Management reviewed ASHP's related policies and statements in responding to the House of Delegates recommendation to address the need for more specific policy addressing the need to incorporate pharmacists in leadership roles in providing oversight and accountability for these medication-related technology and EHR activities. The Council agreed a more strongly worded policy to address the issues and patient safety concerns is needed. The Council, in collaboration with the Section of Pharmacy Informatics and Technology's Chair, decided these policies and statements need to be reviewed in aggregate and the Section will provide proposed language as needed.

Pharmacy's Role in Storage, Handling, and Dispensing of Fecal Matter Transplantation Materials (Recommendation): Scott Anderson (VA)

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

The Council on Therapeutics reviewed the clinical aspects of biome transfers, including vaginal biome transfer and the more commonly used fecal matter transplant (FMT). With the success of FMT in the treatment of resistant *C. difficile* infections, there has been an expanding interest in the treatment of other diseases, including other gastrointestinal maladies, diabetes, obesity, neurologic disorders, and autism, with some or few studies on these emerging areas. There have also been discussions in the literature to determine whether biome transfers (most commonly FMT) should be considered a tissue or a drug, given that the intent is to transfer constructive microbiota from a healthy donor to a sick donor. The Council felt that because FMT is an established treatment and has both therapeutic and practice elements that the Council on Pharmacy Practice should evaluate the need for a policy, as many of the topics discussed are outside the purview of the Council on Therapeutics. Operation logistics discussed included screening and management of donors, protocols including hazardous waste and biohazardous handling of fecal matter, storage and handling, and the role of the pharmacist. Council members who perform FMT at their institutions state that the pharmacy department does not have an integral role, as the transfer is done by a specialty service, such as the gastrointestinal specialist. The Council also recommended education through ASHP's various educational arms.

Reduction of Waste from Single-Dose Vials (Recommendation): Jennifer Sterner Allison (GA)

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

The Council on Pharmacy Practice discussed this topic during Policy Week and drafted the following policy recommendation which will be considered by the House of Delegates at its June 2018 meeting in Denver.

Availability and Use of Appropriate Vial Sizes (Voted 3)

VOTED TO RECOMMEND 3

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste (e.g., multiple-dose vials or single-dose vials of differing doses); further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the appropriate use of single-dose, single-use, and multiple-dose vials.

Pharmacist's Role in Stem Cell Biologicals Preparation and Distribution (Recommendation): Kathy Baldwin (FL)

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

The Section of Clinical Specialists and Scientists Executive Committee and Section on Emerging Sciences will be researching the science and pharmacy practice issues that are involved with Stem Cell Biologicals Preparation and Distribution and potentially develop education and/or materials for this new and exciting area of pharmacy.

Past Chair Role on Councils (Recommendation): 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.

The main intent of your recommendation is to ensure continuity from year to year with the Councils. The creation of a past chair role would provide continuity but there are other means of achieving this goal already in place through ASHP's current appointment process. The ASHP President-Elect takes continuity into account as he or she makes appointments to Councils. Council appointments include a significant number of reappointments which provides stability and continuity from year to year; and the Vice Chair is typically reappointed and serves as the Chair the following year which provides continuity in Council leadership. The President-Elect also takes into account the significant number of new individuals that seek to serve ASHP on Councils, one of the most rewarding volunteer experiences of ASHP. The appointment process is one that effectively balances new and returning Council members.

Using ASHP Policies to Educate All Health Professionals (Recommendation): 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.

ASHP professional policies, statements, and guidelines are widely used by other professions. For example, the ASHP Therapeutic Guidelines on Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery and Therapeutic Monitoring of Vancomycin in Adult Patients: A Consensus Review of the American Society of Health-System Pharmacists, the Infectious Diseases Society of America, and the Society of Infectious Diseases Pharmacists are frequently cited in the literature and included in resources such as the American Hospital Association's Physician Leadership Forum on Antimicrobial Stewardship. ASHP professional policy, statements, and guidelines are available on the ASHP website, but are also published in AJHP online. Additionally, AJHP is open access so these policy documents are widely discoverable and accessible via numerous search engines including Google, Google Scholar, Ovid, EBSCO, and PubMed.

Support Development of Pharmacy Resident Wellness Programs (Recommendation): Dave Hager (WI)

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

ASHP agrees that resilience and well-being of the pharmacy workforce is important. ASHP recently signed on to be involved in the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience – so far ASHP is the only pharmacy organization represented. That effort is broad at this time but over time will narrow to interventions to help clinicians in all phases of their career – student, resident, new practitioner, seasoned practitioner. ASHP will gather information from NAM, share with members, and determine next steps.

Nashville! (Recommendation): Casey White (TN)

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

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

Guidelines for Pharmacist Relations with Industry (Recommendation): Casey White (SCSS)

[Request an update on the status of the Guidelines for Pharmacist Relations with Industry.](#)

The project stalled when a question about standards for residency preceptors was raised. Those revised standards were approved late last year, and some related guidance was revised this spring. The ASHP policy portfolio is expansive, and unfortunately ASHP does not have the resources to respond immediately to changing circumstances. We appreciate it when enthusiastic and informed members alert us to a lagging project and help move it along. The draft guidelines will be posted for public review in September with a goal of completing the drafting by year's end.

Standardization of Collaborative Practice Terminology to Support Provider Status Legislation (Recommendation): 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.

The CDC recently released a guide titled "Advancing Team-Based Care Through Collaborative Practice Agreements." While it does not specifically address an effort to establish consistent terminology, the guide does point out terminology and laws vary widely among states regarding the authority and services provided. ASHP has collaborated with other national and state pharmacy organizations as part of the NASPA Collaborative Practice Workgroup and the NASPA Statewide Protocol Workgroup. The Collaborative Practice Workgroup developed recommendations for what elements of collaborative practice authority should be defined under state law or regulation, and what elements are best left to be determined between pharmacists and other practitioners. The Statewide Protocol Workgroup recommended developing model legislative or regulatory language based on the consensus-based elements of state policies for statewide protocol authority.

ASHP is also a member of the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process Workgroup currently responsible for serving as the steward of the Medication Therapy Management (MTM) definitions and the framework that maps the definitions to SNOMED CT codes. It is expected that the use of SNOMED CT codes for documenting MTM and other advanced practice pharmacist services will expand. Having standardized terms and definitions with corresponding SNOMED CT codes will help to foster consistency in terminology and clarity regarding the aspects of pharmacist services delivered. For the practicing pharmacist, it is imperative that the documentation of pharmacists' patient care is supported by a standardized terminology mapped to SNOMED CT codes and aligned with the Pharmacists' Patient Care Process.

ASHP will continue to work with other stakeholder organizations as noted above and through those efforts seek ways to standardize terminology.

Education for Rare (Orphan) Diseases (Recommendation): Melinda 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.

The Council reviewed ASHP policy 1413, Ensuring Effectiveness, Safety, and Access to Orphan Drug Products, on the recommendation of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel and voted to recommend amending the policy to include language that urges federal review to evaluate whether orphan drug status is being used inappropriately to extend patents and decrease competition, reducing patient access.

In addition, the Council also discussed a requested amendment to ASHP policy 1413 from the House of Delegate to include a clause that advocates being more inclusive of educating pharmacists and other healthcare providers about rare (orphan) diseases. The Council acknowledged that many healthcare providers may not be familiar with rare diseases but that ASHP could meet this need through its various educational avenues.

Dosing Considerations in Extracorporeal Treatment Modalities (Recommendation): Casey White (SCSS)

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

After a literature search, ASHP agrees that there aren't many guidance documents on this topic. We will consider your request among the other guidance documents in the pipeline and consider reaching out to the Society of Critical Care Medicine as a potential collaborator.

Pharmacists Leadership in Compliance and Education for Pharmacist Clinical Services Billing and Reimbursement (Recommendation): 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.

ASHP has several policies on the topic, including ASHP policy positions 1710, Revenue Cycle Compliance and Management, and 1502, Pharmacist Recognition as a Healthcare Provider. ASHP has two resource centers that provide information on the topic, the [Business Management](#) Resource Center and the [Payer Recognition and Reimbursement](#) section of the [Provider Status Readiness](#) Resource Center. In addition, ASHP's online [e-Learning Center](#) offers five free learning experiences on the topic, and the 2017 Midyear Meeting offered several educational sessions at which billing was among the learning objectives, including Reducing Geriatric Patient Risk at the Transition of Care from Hospital to Home, The Next Wave: Specializing Ambulatory Care, and Enhancing Quality of Care: Pharmacist Clinical Documentation in an Integrated EMR System.

Medical Aid in Dying, Hospice, and Palliative Care Education (Recommendation): 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.

This issue, specifically as it relates to palliative sedation, will be explored by the 2017-2018 Section of Ambulatory Practitioners Advisory Group on Pain Management and Palliative Care.

ASHP's Advocacy and PAC Advisory Committee (Recommendation): 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.

The Council on Public Policy developed a new statement on advocacy as a professional responsibility. This new statement will be considered at the upcoming House of Delegates session at ASHP's Summer Meetings.

Pharmacist Prescribing of Controlled Substances (Recommendation): 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 practices acts.

This item was added to the Council on Public Policy agenda for policy week. The council reviewed existing policy on pharmacists' ability to prescribe and discussed whether new policy was needed. The Council believes that existing policy does cover this topic. However, as Congress considers an additional bill to stem the opioid epidemic, ASHP will work with other pharmacy stakeholders to recognize pharmacists' ability to prescribe in certain jurisdictions.

Summer Meeting in Indianapolis (Recommendation): John Hertig (IN), Tate Trujillo (IN), Amy Heck (MI)

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

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

Banning Advertisements for 1-800-Bad-Drug (Recommendation): 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.

During Policy Week, the Council on Public Policy developed new policy that opposes drug litigation ads that may cause patients to discontinue medically necessary drugs unless clear disclaimer language in the form of a warning for patients if they discontinue the medication without seeking advice from their health care provider. This policy will be considered at the upcoming House of Delegates session at ASHP's Summer Meetings.

Antimicrobial Stewardship Program Support (Recommendation): 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.

This topic is of high importance, relevance, and very timely for our members, patients, and healthcare systems. The Council on Pharmacy Practice discussed this issue during its June call and added it to its agenda for Policy Week 2017. The council has decided to take a broader perspective and will review what stewardship means and how we can create policy to encompass all areas of stewardship (such as opioids). We do understand however that antimicrobial stewardship is currently the only program mandated by Joint Commission and that facet does need to be encompassed into the policy.

ASHP Opposes Federal Budgetary Proposals that Impede the Practice of Pharmacy (Recommendation): 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.

ASHP supports adequate funding levels for a number of public health initiatives including, funding for the FDA, funding for PGY2 residency programs and funding to combat the opioid crisis. ASHP does oppose cuts to these and other vital public health initiatives. The President's budget from earlier this year contained a number of very problematic cuts to federal programs. ASHP, working with our allies in Congress, did express concerns over these cuts. It is important to note that we were told very early in the process that these cuts would not pass Congress. The President is free to offer budget suggestions as typically every President does each year, but it is the Congress who will ultimately decide whether and how to make cuts. We remain vigilant against cuts to key public health programs and agencies which are vital to maintaining a safe supply of medications.

Encourage State Affiliate and ASHP Collaboration on Shared Sales of Limited Publications (Recommendation): 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.

ASHP has evaluated shared sales of publications and administered such a program with state affiliates in various forms. The most recent offering was several years ago. Unfortunately it was complicated to administer and few state affiliates participated in it. Earnings made by either ASHP and its state affiliates were nominal. Due to limited participation and the low return on investment, ASHP closed out the program. If KCHP and USHP feel strongly about revisiting the program, we would be open to discussions. ASHP invests in other mechanisms and services to foster collaboration and congruence with state affiliates through the work of the Affiliate Relations Division and the many in-kind services provided to state affiliates throughout the organization.

Simultaneous Leadership in ASHP and State Affiliates (Recommendation): 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.

The ASHP elected positions provide significant professional and organizational input and make policy recommendations to the ASHP Board of Directors and House of Delegates. Discussions by elected leaders and their subsequent recommendations substantially impact the membership, professional policies, educational programs and other activities of ASHP.

It is recognized that elected members have concurrent and other professional/business interests, and that there is a need to have a wide variety of professional and business experiences when participating in policy discussions. However, some of these other professional interests may involve potential or perceived conflicts of interest (COI).

It is important that all elected leaders maintain certain professional, ethical and legal standards to ensure that recommendations and decisions are perceived as objective, honest, and are in the best interests of ASHP and/or the organizations that they serve. COI is an ever-evolving concept, and the need for COI principles and procedures in order to manage COI stems from increased governmental scrutiny of governance and decision making by professional and nonprofit organizations.

ASHP elected leaders have access to sensitive strategic and proprietary information beyond fiduciary information about ASHP and its membership during their times of service. As such, ASHP strives to take affirmative steps to manage and minimize any real, perceived or potential COI situations involving elected leaders. By doing so, the independence and integrity of these leaders and ASHP are maintained.

Simultaneous service, therefore, would not be in the best interests of all parties. ASHP invests in other

mechanisms and services to foster collaboration and congruence with state affiliates including the work of the Affiliate Relations Division and the many in-kind services provided to state affiliates throughout the organization.

Generic Lifesaving Medication Production in the U.S. (Recommendation): 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.

The Council on Public Policy discussed this proposal on its January 2018 conference call. The Council developed two new policies on drug shortages. One policy urges FDA to develop a drug manufacturing quality rating system that rewards companies who utilize manufacturing processes that are of the highest quality. The policy urges FDA to develop incentives for companies to participate. The second policy advocates for policy makers to recognize intravenous fluids as critical public health infrastructure.

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

ASHP agrees with your assessment that recognition of the slate of candidates for President, Board of Directors, and Section Chairs and Directors-at-Large is important. Your recommendation suggested specific ways that ASHP can maintain a consistent approach for candidate recognition during the House of Delegates meetings. ASHP will seek to implement your suggestions as feasible such as projecting candidate's photos for the delegates. Presence of the slate of candidates is not a requirement during House of Delegates meetings, although desired. Thank you for your suggestions which will result in process improvements.

Providing Opportunities for Pharmacists Working in Health Plans and PBMs (Recommendation): 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.

Your recommendation is timely as more ASHP members' organizations develop health plans and PBMs, as well as the growing role of pharmacists supporting the contracting process for their organizations when working with health plans and PBMs. Additionally, we have seen a number of members assume roles that are supportive of or embedded in an Accountable Care Organization where their need to coordinate the role of a 'payer' and a clinician becomes central to their role.

This year at ASHP's invitational Multi-Hospital Pharmacy Executive (MHPE) symposium in October the topic will be PBM management, engagement, and development. This symposium is organized by the Section of Pharmacy Managers Advisory Group on MHPEs, and should also help define opportunities and needs such as the one you have defined in your recommendation.

I will also be sharing your recommendation with the Executive Committees of the sections since the members dealing with these issues may reside or have developed from ambulatory care, clinical specialist, or the practice managers. At this point I can't make a commitment on timing, and I think the mix of potential ASHP members would be diverse, but the subject matter and the business/clinical interface you have described is one that is growing and I look forward to helping develop ideas and opportunities to connect likeminded members in the near future.

Expansion of PGY2 Pain Residency Programs (Recommendation): 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.

ASHP has a content expert panel that has been convened to work on the revision of the PGY2 Pain and Palliative Care competencies, goals and objectives. This group includes the individuals listed below. As you can see, they represent varied practice settings, including the VA. Our goals for this revision included the very flexibility that you described in your recommendation. We are trying to gain consensus on the core requirements and allow for practice differences and uniqueness through the use of electives. This approach is actually going very well and we hope to have a draft available for comment soon. Thank you for your concern and interest in the Pain and Palliative Care competencies, goals, and objectives and the need to address diversity of practice scope.

Publicly Available Quality Metrics for Manufacturers (Recommendation): 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.

This is an area that we are watching closely and agree that it has importance for health-systems. During its January 2018 conference call, the Council on Public Policy developed two new policies around drug shortages. One of them advocates for FDA to develop a drug quality ratings system for drug manufacturers. This policy will be considered at the upcoming House of Delegates at ASHP'S Summer Meetings.

Interprofessional Competencies (Recommendation): Paul Walker (MI)

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

The Council discussed these issues during Policy Week. After review of existing ASHP policy and PGY1 and PGY2 competency area goals and objectives (CAGO) lists, Council members felt that ASHP policy and residency standards were heavily weighted toward interprofessional education. ASHP participated in the National Collaborative for Improving the Clinical Learning Environment (NCICLE) Interprofessional Clinical Learning Environment Symposium, where the intent was to enhance a national conversation that seeks to identify ways to assist clinical learners to embrace interprofessional collaboration and learning. Symposium outcomes will be discussed in a future Council meeting.

Medicines of Animal Origin (Recommendation): Casey White (SCSS)

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

The Council on Pharmacy Practice reviewed this topic during our June call. This topic did not score high enough to be prioritized for Policy Week 2017 but do feel this is a topic that impacts our members and deserves attention before the next June House in 2018.

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

Current Medicare billing practice requires a Medicare-eligible practitioner's NPI to appear on claims – except under Part D, where CMS has made specific provision for the use of pharmacists' NPI numbers on prescription claims. Thus, until pharmacists are Medicare-eligible, they will not be able to use their own NPIs on Medicare claims/orders. At present, the proposed policy would conflict with federal law and would likely add to confusion around appropriate billing practices. However, when pharmacists become Medicare-eligible, such a policy may be beneficial. In the interim, ASHP will continue to advocate for clarity around billing practices, particularly regarding conflicting interpretations from regional Medicare Administrative Contractors.

ASHP House of Delegates Training Materials (Recommendation): Carol Rollins (AZ), Melissa 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.

ASHP currently offers delegates a Welcome Packet, a Chair's Welcome Message, a Chair's Welcome Video, a Chair's Welcome Webinar, and an overview of the ASHP policy process. As noted in the recommendation, none of those resources provides potential delegates an on-the-ground view of what occurs in a House meeting so they can better understand procedures and increase their comfort in volunteering. In response to the insightful suggestion, ASHP has recorded a Delegate Primer and posted in on the ASHP House of Delegates website.

Guidelines for Care of Transgender Patients (Recommendation): OR, SCSS

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.

The Center of Excellence for Transgender Health published in June of 2016 Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Non-binary People but only reference pharmacists in a dispensing role (I have also attached it to this email). ASHP will be reaching out to this organization for discuss potential expansion of existing guidelines to be more comprehensive of the pharmacist and their skill set.

PBM Transparency around DIR Fees (Recommendation): Nishaminy Kasbekar (PA)

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

The Council on Public Policy developed a new policy that advocates for the prohibition of DIR fees. That policy was developed and voted upon by the Council and will be considered for adoption at the 2018 Summer Meetings.

Drug Take-back and Appropriate Disposal (Recommendation): 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.

The Council on Pharmacy Practice did try to incorporate the concept in Policy 1603. The council recognizes that either additional verbiage or another policy may be needed to completely address all of the components of a take-back process and controls associated with the process. CPhP will be discussing this topic more throughout the year and before the next June House in 2018.

Pharmacists' Roles in Mental Health and Illness (Recommendation): Ashley Schaber (USPHS), Julie Groppi (VA), Renee Robinson (USPHS), Heather Ourth (VA), Alice Moss (Navy), Winnie Lok-Park (Air Force), Lara Nichols (AK), Amy Sipe (MO), (COT), Gwendolyn Thompson (Army)

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

The topic of mental health and illness continues to gain recognition of disease state and thus, has treatments available to control symptoms and optimize quality of life for patients. ASHP has interests in not only treating patients with mental illness but also identifying and advocating for widespread recognition within our own professional practice. This topic is of high relevance to our members and patients and CPhP will be discussing the topic throughout the year before the next June House in 2018. ASHP also is working with organizations such as SAMSHA and others to make sure we fully understand the depth of understanding and treatment options for mental illness. We are highly interested in models from the VA and may reach out to some of you to share your knowledge and information.

State Level Provider Status Toolkit (Recommendation): Adam Porath (NV)

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

This issue is already being discussed as part of an internal ASHP team looking at provider status readiness. As you can imagine, provider status is a tremendous professional achievement, however, it also brings with

it some new challenges around credentialing, privileging, third party payers, etc. ASHP is aware of these challenges and has convened an internal working group to address them. A tool kit is among the objectives the group hopes to develop, perhaps as part of a larger resource page on our web site. We are beginning this process by conducting a thorough review of all of our existing resources on provider status and direct patient care, and will use that as a basis to develop a tool kit.

Summer Meetings in Florida (Recommendation): 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.

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

Professional Policies Approved by the 2018 ASHP House of Delegates

Denver, CO

June 5, 2018

Am J Health-Syst Pharm. 2018; 75:e569-73

The new professional policies approved by the ASHP House of Delegates are listed below. Policies 1801–1804 were approved by the virtual House of Delegates in March. Policies 1805–1830 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 “June Board Reports on Councils.” (<https://www.ashp.org/House-of-Delegates/House-of-Delegates-Action-Items>). The complete proceedings of the House of Delegates will be provided to delegates and will be posted on the ASHP Web site.

1801

Unit Dose Packaging Availability

Source: Council on Pharmacy Management

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that reduces medication waste; further,

To urge the Food and Drug Administration to support this goal in the interest of public health and healthcare worker and patient safety.

This policy supersedes ASHP policy 0309

1802

Gene Therapy

Source: Council on Pharmacy Management

To assert that health-system decisions on the selection, use, and management of gene therapy agents should be managed as part of the medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; further,

To advocate that gene therapy be documented in the permanent patient health record; further,

To advocate that documentation of gene therapy in the permanent patient health record accommodate documentation by all healthcare team members, including pharmacists.

This policy supersedes ASHP policy 0103.

1803

Confidence in the U.S. Drug Approval and Regulatory Process

Source: Council on Public Policy

To support and foster legislative and regulatory initiatives designed to improve public and professional confidence in the drug approval and regulatory process in which all relevant data are subject to public scrutiny.

This policy supersedes ASHP policy 9010.

1804

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 advocate healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics; 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.

This policy supersedes ASHP policy 1720.

1805

Medication Formulary System Management

Source: Council on Pharmacy Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare profes-

sionals; and (3) should not be based solely on economic factors.

This policy supersedes ASHP policy 0102.

1806

Manufacturer-sponsored Patient Assistance Programs

Source: Council on Pharmacy Management

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

To advocate expansion of PAPs to inpatient settings; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance the efficiency of PAPs by standardizing application criteria, processes, and forms; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and visibility of PAPs to pharmacy personnel and other healthcare providers; further,

To encourage pharmacy personnel, other healthcare providers, and pharmaceutical manufacturers to work cooperatively to ensure PAPs include the essential elements of pharmacist patient care, are patient-centered, and are transparent; further,

To develop education for pharmacy personnel and other healthcare providers on the risks and benefits of PAPs.

This policy supersedes ASHP policy 1420.

1807

Reimbursement and Pharmacist Compensation for Drug Product Dispensing

Source: Council on Pharmacy Management

To collaborate with payers in developing improved methods of reimbursing pharmacies and pharmacists for the costs of drug products dispensed,

pharmacy and pharmacist services, and associated overhead; further,

To educate pharmacists and stakeholders about those methods.

This policy supersedes ASHP policy 1304.

1808

Patient Access to Pharmacist Care Within Provider Networks

Source: Council on Pharmacy Management

To advocate for laws and regulations that require healthcare payer provider networks to include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits; further,

To advocate for laws and regulations that allow pharmacists and pharmacies to participate as a provider within a healthcare payer's network if the pharmacist or pharmacy meets the payer's criteria for providing those healthcare services; further,

To acknowledge that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality and viability of healthcare services provided; further,

To advocate that healthcare payers be required to disclose to pharmacists and pharmacies applying to participate in a provider network the criteria used to include, retain, or exclude pharmacists or pharmacies.

1809

Health Insurance Policy Design

Source: Council on Pharmacy Management

To advocate that all health insurance policies be designed and coverage decisions made in a way that preserves the patient-practitioner relationship; further,

To advocate that health insurance payers and pharmacy benefit managers provide public transparency

regarding and accept accountability for coverage decisions and policies; further,

To oppose provisions in health insurance policies that interfere with established drug distribution and clinical services designed to ensure patient safety, quality, and continuity of care; further,

To advocate for the inclusion of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

This policy supersedes ASHP policy 1520.

1810

Pharmacy Accreditations, Certifications, and Licenses

Source: Council on Pharmacy Management

To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,

To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidence-based principles of patient safety and quality of care; further,

To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,

To advocate that health-system administrators, including compliance officers and risk managers, allocate the resources required to support medication-use compliance and regulatory demands.

This policy supersedes ASHP policy 1303.

1811

Use of International System of Units for Patient- and Medication-related Measurements

Source: Council on Pharmacy Practice

To advocate that the U.S. healthcare system adopt and only use the International System of Units (SI units) for all patient- and medication-related measurements and calculations; further,

To advocate that healthcare organizations use clinical decision support systems, equipment, and devices that allow input and display of patient- and medication-related measurements and calculations in SI format only; further,

To advocate that health information technology manufacturers utilize only SI units in their product designs for patient- and medication-related measurements; further,

To promote education in the use of SI units and the importance of using SI units to prevent medical errors.

1812

Availability and Use of Appropriate Vial Sizes

Source: Council on Pharmacy Practice

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste and enhance safety; further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the safe and appropriate use of single-dose, single-use, and multiple-dose vials.

1813

Use of Closed-System Transfer Devices to Reduce Drug Waste

Source: Council on Pharmacy Practice

To recognize that a growing body of evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are

used with aseptic technique and following current sterile compounding standards; further,

To foster additional research on and develop standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

1814

Direct and Indirect Remuneration Fees

Source: Council on Public Policy

To advocate that payers and pharmacy benefit managers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated dispensing claims; further,

To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.

1815

Impact of Drug Litigation Ads on Patient Care

Source: Council on Public Policy

To oppose drug litigation advertisements that do not provide a clear and conspicuous warning that patients should not modify or discontinue drug therapy without seeking the advice of their healthcare provider.

1816

Biosimilar Medications

Source: Council on Public Policy

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

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

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

medications that are also determined by the FDA to be interchangeable and therefore supports substitution for the reference product without the intervention of the prescriber; further,

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

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; further,

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

To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA; further,

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

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

This policy supersedes ASHP policy 1509.

1817

340B Drug Pricing Program Sustainability

Source: Council on Public Policy

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

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate with state Medicaid programs to ensure that reimbursement policies promote 340B program stability; further,

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

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

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

To educate health-system administrators, risk managers, and pharmacists about the resources required to support 340B program compliance and documentation; further,

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

This policy supersedes ASHP policy 1407.

**1818
Federal Quality Rating Program for Pharmaceutical Manufacturers**

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) assign quality ratings to pharmaceutical manufacturers based on the quality of their manufacturing processes, sourcing of active pharmaceutical ingredients and excipients, selection of contract manufacturers, and business continuity plans; further,

To advocate that the FDA consider offering incentives for manufacturers to participate in the program.

**1819
Intravenous Fluid Manufacturing Facilities as Critical Public Health Infrastructure**

Source: Council on Public Policy

To advocate that federal and state governments recognize intravenous fluid and associated supply manufacturing facilities as critical public health infrastructure.

**1820
Medical Devices**

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

This policy supersedes ASHP policy 9106.

**1821
Ensuring Effectiveness, Safety, and Access to Orphan Drug Products**

Source: Council on Therapeutics

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

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

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

To advocate that health policymakers, payers, and pharmaceutical manu-

facturers ensure continuity of care and patient access to orphan drug products; further,

To advocate federal review to evaluate whether orphan drug designation is being used inappropriately to receive FDA approval, extend patents, decrease competition, or limit discounts, thereby reducing patient access.

This policy supersedes ASHP policy 1413.

**1822
Rational Use of Medications**

Source: Council on Therapeutics

To promote evidence-based prescribing and deprescribing for indication, efficacy, safety, duration, cost, and suitability for the patient; further,

To advocate that pharmacists lead interprofessional efforts to promote the rational use of medications, including engaging in strategies to monitor, detect, and address patterns of irrational medication use in patient populations.

This policy supersedes ASHP policy 1312.

**1823
Responsible Medication-related Clinical Testing and Monitoring**

Source: Council on Therapeutics

To recognize that overuse of clinical testing leads to unnecessary costs, waste, and patient harm; further,

To encourage pharmacist accountability and engagement in interprofessional efforts to promote the judicious use of clinical testing and monitoring; further,

To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate ordering of medication-related procedures and tests; further,

To promote the use of interoperable health information technology services and health information exchanges to decrease unnecessary testing.

1824**Use of Biomarkers in Clinical Practice***Source: Council on Therapeutics*

To promote appropriate, evidence-based use of biomarkers in clinical practice; further,

To encourage research that evaluates the clinical and safety implications of biomarkers in the care of patients and to guide clinical practice; further,

To promote Food and Drug Administration qualified biomarkers in drug development, regulation, and use in clinical practice; further,

To foster the development of timely and readily available resources about biomarkers and their evidence-based application in clinical practice.

1825**Clinician Well-being and Resilience***Source: Council on Education and Workforce Development*

To affirm that burnout adversely affects an individual's well-being and healthcare outcomes; further,

To acknowledge that the healthcare workforce encounters unique stressors throughout their education, training, and careers that contribute to burnout; further,

To declare that healthcare workforce well-being and resilience requires shared responsibility among healthcare team members and between individuals and organizations; further,

To encourage individuals to embrace well-being and resilience as a personal responsibility that should be supported by organizational culture; further,

To encourage the development of programs aimed at prevention, recognition, and treatment of burnout, and to support participation in these programs; further,

To encourage education and research on stress, burnout, and well-being; further,

To collaborate with other professions and stakeholders to identify ef-

fective preventive and treatment strategies at an individual, organizational, and system level.

1826**Student Pharmacist Drug Testing***Source: Council on Education and Workforce Development*

To advocate for the use of pre-enrollment, random, and for-cause drug testing throughout pharmacy education and pharmacy practice experiences, based on defined criteria with appropriate testing validation procedures; further,

To encourage colleges of pharmacy to develop policies and processes to identify impaired individuals; further,

To encourage colleges of pharmacy to facilitate access to and promote programs for treatment and to support recovery; further,

To encourage colleges of pharmacy to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

1827**Collaboration on Experiential Education***Source: Council on Education and Workforce Development*

To encourage practitioner contributions to pharmacy education; further,

To encourage pharmacists and pharmacy leaders to recognize their professional responsibility to contribute to the development of new pharmacy practitioners; further,

To promote collaboration of experiential teaching sites with the colleges of pharmacy (nationally or regionally), for the purpose of fostering preceptor development, standardization of experiential rotation schedule dates and evaluation tools, and other related matters; further,

To encourage colleges of pharmacy and health systems to define and develop collaborative organizational rela-

tionships that support patient care and advance the missions of both institutions in a mutually beneficial manner.

This policy supersedes ASHP policies 0315 and 0804.

1828**Promoting the Image of Pharmacists and Pharmacy Technicians***Source: Council on Education and Workforce Development*

To promote the professional image of pharmacists and pharmacy technicians who work in all settings of health systems to the general public, public policymakers, payers, other healthcare professionals, and healthcare organization decision-makers.

This policy supersedes ASHP policy 0703.

1829**Pharmacy Training Models***Source: Council on Education and Workforce Development*

To promote pharmacy training models that: (1) provide experiential and residency training in interprofessional patient care; (2) use the knowledge, skills, and abilities of student pharmacists and residents in providing direct patient care; and (3) promote use of innovative and contemporary learning models; further,

To support the assessment of the impact of these pharmacy training models on the quality of learner experiences and patient care outcomes.

This policy supersedes ASHP policy 1316.

1830**ASHP Statement on Advocacy as a Professional Obligation***Source: Council on Public Policy*

To approve the ASHP Statement on Advocacy as a Professional Obligation.