



# House of Delegates Session—2015

June 7 and 9, 2015  
Denver, Colorado

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Proceedings of the 67th annual session  
of the ASHP House of Delegates,  
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*PAUL W. ABRAMOWITZ, SECRETARY*

The 67th annual session of the ASHP House of Delegates was held at the Colorado Convention Center, in Denver, Colorado, in conjunction with the 2015 Summer Meetings.

## **First meeting**

The first meeting was convened at 1:00 p.m. Sunday, June 7, by Chair of the House of Delegates James A. Trovato. Chair Trovato introduced the persons seated at the head table: Gerald E. Meyer, Immediate Past President of ASHP and Vice Chair of the House of Delegates; Christene M. Jolowsky, 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 Trovato welcomed the delegates and described the purposes and functions of the House. He emphasized that the House has considerable responsibility for establishing policy related to ASHP professional pursuits and pharmacy practice in hospitals and health systems. He reviewed the general procedures and processes of the House of Delegates.

The roll of official delegates was called. A quorum was present, including 196 delegates representing 49 states and the District of Columbia (no delegates from Hawaii or Puerto Rico were present), as well as the federal services, chairs of ASHP sections and forums, ASHP officers, members of the Board of Directors, and ASHP past presidents (see Appendix I for a complete roster of delegates).

Chair Trovato reminded delegates that the report of the 66th 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 66th House of Delegates session were received without objection.

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

**Report of the Committee on Nominations.** Chair Trovato called on Robert Adamson for the report of the Committee on Nominations (Appendix III).<sup>a</sup> Nominees were presented as follows:

### *President 2016–2017*

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

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

### *Chair, House of Delegates 2015–2018*

**Amber J. Lucas, Pharm.D., BCPS, FASHP,** Clinical Pharmacist, Olathe Medical Center, Olathe, KS

**Natasha Nicol, Pharm.D., FASHP,** Director of Global Patient Safety Affairs, Cardinal Health, Pawleys Island, SC

### *Board of Directors, 2016–2019*

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

**Todd A. Karpinski, Pharm.D., M.S., FASHP,** Chief Pharmacy Officer, Froedtert and the Medical College of Wisconsin, Menomonee Falls, WI

**Seena L. Haines, Pharm.D., BCACP, FASHP, BC-ADM, CDE, FAPhA,** Professor of Pharmacy Practice, Associate Dean, Palm Beach Atlantic University, Gregory School of Pharmacy, West Palm Beach, FL

**Jennifer M. Schultz, Pharm.D., FASHP,** Clinical Pharmacy Supervisor and Residency Program Director, Bozeman Deaconess Health Services, Bozeman, MT

A “Meet the Candidates” session to be held on Monday, June 8, was announced. Chair Trovato announced the candidates for the executive committees of the five sections of ASHP.

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

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

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

The ASHP Bylaws [Section 7.3.1.1] require the Board of Directors to reconsider an amended policy before it becomes final. The Board reported the results of its “due consideration” of amended policies during the second meeting of the House; see that section of these Proceedings for the final disposition of amended policies.)

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Kathleen S. Pawlicki, Board Liaison to the Council on Public Policy, presented the Council’s Policy Recommendations 1 through 9.

#### \*1. Pharmacist Participation in Health Policy Development

To ~~urge~~ *advocate* that pharmacists to participate with policy-makers and stakeholders in the development of medication health-related health policies at the national, state, and community levels; further,

To develop tools and resources to assist pharmacists in fully participating in health policy development at all levels.

#### \*2. Pharmacist Recognition as a Healthcare Provider

To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as healthcare providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as healthcare providers, improve access to patient care and bridge existing gaps in healthcare; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

To advocate for *sustainable* compensation and *standardized billing processes used by payers* for pharmacist services by ~~any~~ *all* available payment programs.

(Note: This policy would supersede ASHP policy 1307.)

#### \*3. Pharmaceutical Product and Supply Chain Integrity

To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thor-

oughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate *for improved transparency* so that drug product labeling include a readily available means to retrieve the *name and* location of the facility that manufactured the specific lot of the product; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product *and its raw materials*; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

(Note: This policy would supersede ASHP policy 0907.)

#### 4. Patient Adherence Programs as Part of Health Insurance Coverage

To advocate for the pharmacist’s role in patient medication adherence programs that are part of health insurance plans; further,

To advocate those programs that (1) maintain the direct patient pharmacist relationship; (2) are based on the pharmacist’s knowledge of the patient’s medical history, indication for the prescribed medication, and expected therapeutic outcome; (3) use a communication method desired by the patient; (4) are consistent with federal and state regulations for patient confidentiality; and (5) permit dispensing of partial fills or overfills of prescription medications in order to synchronize medication refills and aid in medication adherence.

(Note: This policy would supersede ASHP policy 0116.)

#### \*5. Statutory Protection for Medication-Error Reporting

To collaborate with other healthcare providers, professions, and stakeholders to advocate and support state and federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and healthcare providers; further,

To seek state and federal liability protection for medication-error reporting that is similar in concept to that which applies to reporting safety incidents and accidents in the aviation industry.

*To provide education on the role that patient safety organizations play in liability protection.*

(Note: This policy would supersede ASHP policy 0011.)

#### **\*6. Premarketing Comparative Clinical Studies**

To advocate that the Food and Drug Administration have the flexibility to decrease the requirement for placebo-controlled studies and correspondingly impose a requirement for comparative clinical trials.

(Note: This policy would supersede ASHP policy 0514.)

#### **7. Funding, Expertise, and Oversight of State Boards of Pharmacy**

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

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

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

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

(Note: This policy would supersede ASHP policy 0518.)

#### **8. Support for FDA Expanded Access (Compassionate Use) Program**

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the sole mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to such drugs under the FDA Expanded Access Program; further,

To advocate that IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol.

#### **9. Approval of Biosimilar Medications**

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

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

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

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

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

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

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

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

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

(Note: This policy would supersede ASHP policy 1409.)

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Paul W. Bush, Board Liaison to the **Council on Therapeutics**, presented the Council's Policy Recommendations 1 through 8.

### **\*1. Naloxone Availability**

To recognize the potential public health benefits of broader use of naloxone for opioid reversal by properly trained individuals; further,

To support efforts to safely expand access to naloxone; further,

To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone ~~only~~ after *receiving counseling by a healthcare professional on proper administration, safe use, and appropriate follow-up care*; further,

To foster education on the role of naloxone in opioid reversal *and its proper administration, safe use, and appropriate follow-up care*; further,

*To support state efforts to authorize pharmacists' prescriptive authority for naloxone for opioid reversal.*

### **\*2. Complementary and Alternative Medicine in Patient Care**

To promote awareness of the impacts of complementary and alternative (CAM) products on patient care, particularly ~~regarding~~ drug interactions, ~~and~~ medication safety concerns, *and the risk of contamination and variability in active ingredient content*; further,

To advocate for the documentation of CAM products in the ~~electronic~~ health record to improve patient safety; further,

To advocate for the inclusion of information about CAM products and their characteristics in medication-related databases; further,

To provide education on the impacts of CAM products on patient care in healthcare organizations; further,

To foster the development of up-to-date and readily available resources about CAM products, ~~with special consideration to drug interactions and medication safety.~~

### **3. Development of Abuse-Resistant Narcotics**

To advocate that the Food and Drug Administration investigate the efficacy of abuse-resistant formulations in preventing prescription drug abuse.

### **4. Quality Patient Medication Information**

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, and simplicity of written patient medication information (PMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level, for PMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of PMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly accessible central repository of PMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of PMI.

(Note: This policy would supersede ASHP policy 1012.)

### **5. Safety and Effectiveness of Ethanol Treatment for Alcohol Withdrawal Syndrome**

To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to treat AWS; further,

To educate clinicians about the availability of alternative therapies for AWS.

(Note: This policy would supersede ASHP policy 1010.)

### **6. Research on Drug Use in Obese Patients**

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in obese patients to facilitate safe and effective dosing of medications in this patient population, especially for medications most likely to be affected by obesity; further,

To encourage manufacturers to include in the Food and Drug Administration (FDA) – approved labeling detailed information on characteristics of individuals enrolled in drug dosing studies; further,

To advocate that the FDA develop guidance for the design and reporting of studies that support dosing recommendations in obese patients; further,

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

To encourage independent research on the clinical significance of obesity on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms.

(Note: This policy would supersede ASHP policy 1013.)

### \*7. Chemotherapy Parity

To advocate that all prescription insurance payers design plans so that patient cost sharing for oral chemotherapy be equivalent regardless of route of administration is no higher than that for intravenous chemotherapy; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of oral chemotherapy agents regardless of route of administration.

### \*8. Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship

To strongly advocate involvement of pharmacists in the clarification of penicillin allergy, intolerance, and adverse drug events; further,

To advocate for documentation of penicillin allergy, *intolerance, reactions, and severity* in the medical record to facilitate appropriate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing in appropriate candidates when clinically indicated to reduce the incidence of inappropriate optimize antimicrobial selection.

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Ranee M. Runnebaum, Board Liaison to the **Council on Education and Workforce Development**, presented the Council's Policy Recommendations 1 and 2.

#### 1. Developing Leadership Competencies

To work with healthcare organization leadership to foster opportunities for pharmacy practitioners to move into leadership roles; further,

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

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

To encourage colleges of pharmacy and ASHP state affiliates to collaborate in fostering student leadership skills through development of co-curricular leadership opportunities, leadership conferences, and other leadership promotion programs; further,

To reaffirm that residency programs should develop leadership skills through mentoring, training, and leadership opportunities; further,

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

(Note: This policy would supersede ASHP policy 0509.)

### \*2. Pharmacy Technician Training and Certification

To advocate that pharmacy technicians be required to have completed a pharmacy technician training program accredited by the Pharmacy Technician Accreditation Commission (PTAC) and to obtain and maintain Pharmacy Technician Certification Board certification; further,

To support the position that by the year 2020, the completion of an ASHP/ACPE-accredited pharmacy technician training program be required to obtain Pharmacy Technician Certification Board certification for all new pharmacy technicians entering the workforce; further,

To foster expansion of ASHP-ACPE PTAC accredited pharmacy technician training programs.

(Note: This policy would supersede ASHP policies 1015 and 0702.)

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Donald E. Letendre, Board Liaison to the **Council on Pharmacy Management**, presented the Council's Policy Recommendations 1 through 5.

#### 1. Impact of Insurance Coverage Design on Patient Care Decision

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

(Note: This policy would supersede ASHP policy 1017.)

#### \*2. Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs

To advocate that pharmacists or *pharmacy technicians* ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist-patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist-patient relationship.

(Note: This policy would supersede ASHP policy 0603.)

### \*3. Disposition of Illicit Substances

To ~~encourage~~ *advocate that* healthcare organizations *be required* to develop procedures for the disposition of illicit substances brought into a facility ~~by patients~~ that ensure compliance with applicable laws and accreditation standards; further,

To ~~encourage~~ *advocate that* healthcare organizations *be required* to include pharmacy leaders in formulating such procedures.

### \*4. Pharmacist's Role in Population Health Management

To recognize the importance of medication management in patient-care outcomes and the vital role of pharmacists in population health management; further,

To encourage healthcare organizations to engage *pharmacists and* pharmacy leaders in identifying appropriate patient cohorts, anticipating their healthcare needs, and implementing the models of care that optimize outcomes for patients and the healthcare organization; further,

To encourage the development of complexity index tools and resources to support the identification of high-risk, high-cost, and other patient cohorts to facilitate patient-care provider panel determinations and workload balancing; further,

To promote collaboration among members of the interprofessional healthcare team to develop meaningful measures of individual patient and population care outcomes; *further,*

*To advocate for education for pharmacists in their role in population health management.*

### 5. ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

To approve the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive.

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Steve S. Rough, Board Liaison to the **Council on Pharmacy Practice**, presented the Council's Policy Recommendations 1 through 10.

### \*1. Support for the Second Victim of Medical Errors

To acknowledge that *the patient is the primary victim in any patient-related event, and that involvement in a medical error, unanticipated adverse patient event, and/or patient-related injury may cause* healthcare personnel ~~may~~ to become second victims of medical errors; further,

To recognize that a just culture ~~environment~~ and a *healthy culture of safety* ~~must include~~ *embrace* a support system for second victims; further,

To encourage healthcare organizations to establish programs to support second victims; further,

To educate healthcare professionals (*including those in training*), *health organization administrators, and regulatory agencies* about the second-victim effect and available resources.

### \*2. Standardization of Doses

To recognize that standardization of medication doses ~~within healthcare organizations~~ reduces medication errors and improves information technology interoperability, operational efficiency, and transitions of care; further,

To encourage ~~healthcare organizations to develop~~ *development of universal* standardized doses for specific ~~to their~~ patient populations; further,

To *encourage healthcare organizations to adopt standardized doses and to promote* publication and education about best practices ~~in standardizing medication doses.~~

### 3. Prescription Drug Abuse

To affirm that pharmacists have leadership roles in recognition, prevention, and treatment of prescription drug abuse; further,

To promote education on prescription drug abuse, misuse, and diversion-prevention strategies.

### \*4. Pharmacist's Role in Urgent and Emergency Situations

To affirm that pharmacists should participate in planning and providing emergency treatment team services; further,

To advocate that pharmacists participate in decision-making about the ~~contents of code carts, emergency medication kits and trays, and the role of pharmacists,~~ *medications and supplies* used in medical emergencies; further,

To advocate that pharmacists serve ~~on cardiopulmonary resuscitation and rapid response teams~~ *in all emergency responses*, and that those pharmacists receive appropriate training and maintain appropriate certifications.

### 5. Excipients in Drug Products

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

(Note: This policy would supersede ASHP policy 0808.)

## 6. Online Pharmacy and Internet Prescribing

To support efforts to regulate prescribing and dispensing of medications via the Internet; further,

To support legislation or regulation that requires online pharmacies to list the states in which the pharmacy and pharmacists are licensed, and, if prescribing services are offered, requires that the sites (1) ensure that a legitimate patient-prescriber relationship exists (consistent with professional practice standards) and (2) list the states in which the prescribers are licensed; further,

To support mandatory accreditation of online pharmacies by the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites or Veterinary-Verified Internet Pharmacy Practice Sites; further,

To support appropriate consumer education about the risks and benefits of using online pharmacies; further,

To support the principle that any medication distribution or drug therapy management system must provide timely access to, and interaction with, appropriate professional pharmacist patient-care services.

(Note: This policy would supersede ASHP policy 0523.)

## \*7. Standardization of Small-Bore Connectors To Avoid Wrong-Route Errors

To *advocate for support the* use of medication administration device connectors and fittings that are designed to prevent misconnections and wrong-route errors; further,

To encourage healthcare organizations to prepare for safe transition to use of medication delivery device connectors and adapters that meet International Organization for Standardization standards; further,

To *oppose the use of syringes with Luer fittings for other than intravascular or hypodermic routes of administration;* further,

To identify and promote the implementation of best practices for preventing wrong-route errors.

## 8. Medication Safety Officer's Role

To discontinue ASHP policy 1019, which reads:

To advocate that accountability for development and maintenance of a medication safety program in hospitals and health systems be assigned to a qualified individual (i.e., a medication safety officer or leader of a medication safety team); further,

To advocate that individuals in these roles have the authority and autonomy to establish priorities for medication-use

safety and make the necessary changes as authorized by the medical staff committee responsible for medication-use policy; further,

To affirm that pharmacists are uniquely prepared by education, experience, and knowledge to assume the role of medication safety officer or other leadership role in all activities that ensure the safety, effectiveness, and efficiency of the medication-use process; further,

To support all pharmacists in their leadership roles in organizational medication-use safety, reflecting their authority over and accountability for the performance of the medication-use process.

## 9. Pharmacist Role in Capital Punishment

To acknowledge that an individual's opinion about capital punishment is a personal moral decision; further,

To oppose pharmacist participation in capital punishment; further,

To reaffirm that pharmacists have a right to decline to participate in capital punishment without retribution.

(Note: This policy would supersede ASHP policy 8410.)

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

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

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Paul W. Bush, Board Liaison to the Section of Pharmacy Informatics and Technology, then moved adoption of the Section's policy recommendation, "ASHP Statement on the Pharmacist's Role in Clinical Informatics." Delegates voted to approve the recommendation.

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**Statements of Candidates for Chair of House.** Candidates for the Chair of the House of Delegates made brief statements to the House of Delegates.

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

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

The meeting adjourned at 4:15 p.m.

## Second meeting

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

**Election of House Chair.** Chair Trovato announced the appointment of alternate delegates as tellers to monitor and report on the election of the Chair of the House of Delegates. Those appointed were Ernest Anderson (MA), James Cattin (ME), Melissa Carlson (MN), Scott Anderson (VA), Anne Policastri (KY), and Jennifer Towle (NH). Chair Trovato instructed tellers and delegates on the process for electronic voting for the office of House Chair. After the voting process, tellers left the assembly to prepare their report while the business of the House proceeded.

**Report of the Committee on Resolutions.** President Jolowsky again presented the Report of the Committee on Resolutions (Appendix II). Monique Bonhomme (DC), one of the Resolution's submitters, moved that the Resolution be referred to the appropriate ASHP committee or task force, as determined by the Board of Directors, for further study. The motion was seconded and the delegates voted to refer the Resolution.

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

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

**Board of Directors duly considered matters.** Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 9 to "duly consider" the policies amended at the first meeting. The Board reported on the 17 professional policies that were amended at the first House meeting. The Board accepted all amendments to policy recommendations, with minor editorial changes to four as follows.

Council on Public Policy 6, "Premarketing Comparative Clinical Studies": The Board duly considered and agreed with the amended language, with the minor editorial change of replacing "flexibility" with "authority" to reflect that the amended language no longer presents a choice between two options, so the policy would read:

To advocate that the Food and Drug Administration have the authority to impose a requirement for comparative clinical trials.

Council on Therapeutics Policy 1, "Naloxone Availability": The Board duly considered and agreed with the amended language, with the minor editorial changes of replacing "counseling" with

"education" in the third clause and "prescriptive authority" with "prescribing authority" in the final clause to be consistent with other ASHP policy, so the policy would read:

To recognize the potential public health benefits of naloxone for opioid reversal; further,

To support efforts to safely expand access to naloxone; further,

To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone after receiving education; further,

To foster education on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care; further,

To support state efforts to authorize pharmacists' prescribing authority for naloxone for opioid reversal.

Council on Education and Workforce Development Policy 2, "Pharmacy Technician Training and Certification": The Board duly considered and agreed with the amended language, with minor editorial changes to the first clause to spell out the name of the Accreditation Council for Pharmacy Education, so the policy would read:

To support the position that by the year 2020, the completion of a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required to obtain Pharmacy Technician Certification Board certification for all new pharmacy technicians entering the workforce; further,

To foster expansion of ASHP-ACPE accredited pharmacy technician training programs.

Council on Pharmacy Management Policy 4, "Pharmacist's Role in Population Health Management": The Board duly considered and agreed with the amended language, with minor editorial changes to the final clause, so the policy would read:

To recognize the importance of medication management in patient-care outcomes and the vital role of pharmacists in population health management; further,

To encourage healthcare organizations to engage pharmacists and pharmacy leaders in identifying appropriate patient cohorts, anticipating their healthcare needs, and implementing the models of care that optimize outcomes for patients and the healthcare organization; further,

To encourage the development of complexity index tools and resources to support the identification of high-risk, high-cost, and other patient cohorts to facilitate patient-care provider panel determinations and workload balancing; further,

To promote collaboration among members of the interprofessional healthcare team to develop meaningful measures of individual patient and population care outcomes; further,

To advocate for education to prepare pharmacists for their role in population health management.

Council on Pharmacy Practice Policy 1, “Support for Second Victims”: The Board duly considered and agreed with the amended language, with minor editorial changes to clarify what was meant by “patient-related event” in the first clause, so the policy would read:

To acknowledge that the patient is the primary victim in any medical error, unanticipated adverse patient event, or patient-related injury; further,

To acknowledge that involvement by healthcare personnel in such events may cause them to become second victims; further,

To recognize that a just culture and a healthy culture of safety embrace a support system for second victims; further,

To encourage healthcare organizations to establish programs to support second victims; further,

To educate healthcare professionals (including those in training), health organization administrators, and regulatory agencies about the second-victim effect and available resources.

Because the Board accepted all House-amended language, no action by the House was necessary to make these policies final.

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**New Business.** Chair Trovato announced that, in accordance with Article 7 of the Bylaws, there was one item of New Business to be considered. Chair Trovato called on Diane Fox (TX) to introduce the item of New Business, “Controlled Substance Accessibility” (Appendix IX). Following discussion, the item was approved for referral. It reads as follows:

#### *Controlled Substance Accessibility*

##### Motion

ASHP should collaborate with other national healthcare organizations, the Drug Enforcement Administration, the National Wholesale Drug Association, the National Association of Chain Drug Stores, and other stakeholders to investigate the inconsistencies in patient access to pain medications and develop strategies to meet legitimate pain care needs for patients.

##### Background

Health System patients have reported extreme difficulty in access to pain medications, especially hydrocodone containing products across the United States. The inability to obtain these necessary medications is resulting in disruption of pain

management for patients transitioning from acute care settings to the ambulatory setting. This issue is becoming a major public health problem in the United States. In addition, patients who attempt to find legitimately prescribed pain therapy have been labeled “drug seekers” and are prevented from obtaining these medications at local drug stores. Health System pharmacies have begun filling outpatient pain medication prescriptions for their patients which has jeopardized the availability of pain therapy for inpatients due to allocations and medication shortages. ASHP policy 1106, Pain Management, supports appropriate pain management strategies and as such; ASHP should take the lead in increasing the access to pain medications for legitimate pain therapy. Identifying the factors contributing to decreased access and working to resolve them is a healthcare priority for the benefit of our patients.

##### Suggested Outcomes

1. ASHP should aggressively work with other interested parties, such as health-system pharmacies, healthcare organizations, wholesalers, chain drug stores, and the Drug Enforcement Administration to determine why these medications are not accessible and to patients with legitimate healthcare needs and develop plans to resolve the inaccessibility problem.
2. ASHP should develop a repository of specific patient experiences to use in telling the story.
3. ASHP should advocate for changing all policies that result in inaccessibility to legitimate pain management therapy for patients.

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

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

As a token of appreciation on behalf of the Board of Directors and members of ASHP, Chair Trovato presented Immediate Past President Jolowsky with an inscribed gavel commemorating her term of office. Ms. Jolowsky recognized the service of Chair Trovato as Chair of the House of Delegates and a member of the Board of Directors.

Chair Trovato recognized Gerald Meyer’s years of service as Chair of the House of Delegates and a member of the Board, as well as in various presidential capacities, as Chair of the Board and as Vice Chair of the House of Delegates.

Chair Trovato then installed the chairs of ASHP’s sections and forums: Kelly Eplen, Section of Ambulatory Care Practitioners; Curtis Collins, Section of Clinical Specialists and Scientists; Emily Alexander, Section of Inpatient Care Practitioners; Brandon Ordway, Section of Pharmacy Informatics and Technology; James Hoffman, Section of Pharmacy Practice Managers; Joshua Fleming, New Practitioners Forum; and

Kristina Lantis, Pharmacy Student Forum. Chair Trovato then recognized the remaining members of the executive committees of sections and forums.

**Results of Election.** Chair Trovato reported the results of the election and announced that Amber J. Lucas had been elected Chair of the House.

**Installation.** Chair Trovato then installed John A. Armitstead as President of ASHP, Tim R. Brown and Lea S. Eiland as members of the Board of Directors (Appendix X), and Amber J. Lucas

as Chair of the House of Delegates. (See Appendix XI for the Inaugural Address of the Incoming President.)

**Adjournment.** The 67th annual session of the House of Delegates adjourned at 5:45 p.m.

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<sup>a</sup>The Committee on Nominations consisted of Robert Adamson, Chair (NJ); Christene Jolowsky, Vice Chair (MN); Jill Bates (NC); Leigh Briscoe-Dwyer (NY); Erin Fox (UT); Jamie Sinclair (MN); and Donna Soflin (NE).

**HOUSE OF DELEGATES**  
**James Trovato, Chair**  
**Gerald Meyer, Vice Chair**  
**Denver, Colorado**  
**June 7 & 9, 2015**  
**FINAL ROSTER**

<sup>1</sup>Sat in Sunday House Meeting only  
<sup>2</sup>Sat in Tuesday House Meeting only

<b>OFFICERS AND BOARD OF DIRECTORS</b>			
Christene Jolowsky, President			
John Armitstead, President-Elect			
Gerald Meyer, Immediate Past President			
James Trovato, Chair, House of Delegates			
Philip Schneider, Treasurer			
Paul Abramowitz, Chief Executive Officer			
Steve Rough, Board Liaison, Council on Pharmacy Practice			
Ranee Runnebaum, Board Liaison, Council on Education and Workforce Development			
Donald Letendre, Board Liaison, Council on Pharmacy Management			
Kathleen Pawlicki, Board Liaison, Council on Public Policy			
Kelly Smith, Board Liaison, Commission on Affiliate Relations			
Paul Bush, Board Liaison, Council on Therapeutics			
<b>PAST PRESIDENTS</b>			
Roger W. Anderson	Marianne Ivey	Sara White	
Daniel Ashby	Stan Kent	T. Mark Woods	
Kevin Colgan	James McAllister, III	David Zilz	
Debra Devereaux	Philip J. Schneider		
Diane Ginsburg	Steven Sheaffer		
Harold Godwin	Thomas Thielke		
<b>STATE</b>	<b>DELEGATES</b>		<b>ALTERNATES</b>
<b>Alabama (3)</b>	Kimberley Benner Pamela Stamm Whitney White		
<b>Alaska (2)</b>	Shawn Bowe Sara Doran		
<b>Arizona (3)</b>	Melinda Throm Burnworth Christi Jen Carol Rollins		
<b>Arkansas (2)</b>	Zhiva Brown Rayanne Story		

<b>STATE</b>	<b>DELEGATES</b>	<b>ALTERNATES</b>
<b>California (8)</b>	Christine Antczak Annet Arakelian Victoria Ferraresi Brian Kawahara Elaine Law Julie Lenhart Stacey Raff Kethen So	
<b>Colorado (3)</b>	Ashley Mains Joel Marrs	
<b>Connecticut (3)</b>	Molly Leber Lorraine Lee	
<b>Delaware (2)</b>	Francine Farnsworth Lisa Deal	
<b>Florida (5)</b>	Deborah Brown Jennifer Burnette Christine Gegeckas Suzanne Turner Richard Montgomery <sup>1</sup> Antonia Zapantis <sup>2</sup>	
<b>Georgia (3)</b>	Michael Melroy Christy Norman Rondell Jagers	
<b>Idaho (2)</b>	Michael Dickens Elizabeth Thompson	
<b>Illinois (5)</b>	Travis Hunerdosse Ann Jankiewicz Despina Kotis Jennifer Phillips Carrie Sincak	
<b>Indiana (3)</b>	Denise Fields John Hertig Amy Hyduk	
<b>Iowa (3)</b>	John Hamiel Lisa Mascardo David Weetman	
<b>Kansas (3)</b>	Christopher Bell Gregory Burger Amber Lucas	
<b>Kentucky (3)</b>	Margo Ashby Megan Brafford Catherine Shely	
<b>Louisiana (3)</b>	Michael Cockerham Tommy Mannino Jennifer Smith	

<b>STATE</b>	<b>DELEGATES</b>	<b>ALTERNATES</b>
<b>Maine (2)</b>	Paul Barrett Tyson Thornton	
<b>Maryland (4)</b>	Patricia Grunwald Asha Tata Kristine Parbuoni Brian Watson	
<b>Massachusetts (4)</b>	Snehal Bhatt Nicole Clark Margarita DiVall Ross Thompson	
<b>Michigan (4)</b>	Ryan Bickel Gary Blake Peggy Malvorh Michael Ruffing	
<b>Minnesota (3)</b>	Lisa Gersema <sup>1</sup> Kristi Gullickson <sup>2</sup> Paul Krogh John Pastor	
<b>Mississippi (2)</b>	Kristie Gholson Wesley Pitts	
<b>Missouri (3)</b>	Nicole Allcock Joel Hennenfent Daniel Good	
<b>Montana (2)</b>	Lonnye Finneman Amanda Patel	
<b>Nebraska (3)</b>	Michele Poepping-Faulkner Donna Soflin Jerome Wohleb	
<b>Nevada (2)</b>	Adam Porath	
<b>New Hampshire (2)</b>	David DePiero Elizabeth Wade	
<b>New Jersey (4)</b>	Robert Adamson Luigi Brunetti Timothy Reilly Paul Goebell, III	
<b>New Mexico (2)</b>	Stephen Adams Juliann Horne	
<b>New York (5)</b>	Joe Pinto Vickie Powell <sup>2</sup> Stephanie Seyse Elizabeth Shlom Mark Sinnett <sup>1</sup>	

<b>STATE</b>	<b>DELEGATES</b>	<b>ALTERNATES</b>
<b>North Carolina (4)</b>	Debby Cowan <sup>2</sup> Stephen Eckel Robert Granko Mary Parker <sup>1</sup> Dennis Williams	
<b>North Dakota (2)</b>	Maari Loy	
<b>Ohio (5)</b>	Kathleen Donley Margaret Huwer Karen Kier Scott Knoer Julie Zaucha	
<b>Oklahoma (3)</b>	Ann Lloyd Edna Patatianian Darin Smith	
<b>Oregon (3)</b>	Kristina Butler Deanna Moretz Michelle Murray	
<b>Pennsylvania (5)</b>	Angela Bingham <sup>2</sup> Rick Demers <sup>1</sup> Nishaminy Kasbekar Patricia Kienle Richard Pacitti Jean Scholtz	
<b>Rhode Island (2)</b>	Ewa Dwierzynski Linda Nelson	
<b>South Carolina (3)</b>	Heather Easterling Natasha Nicol Robert Spires	
<b>South Dakota (2)</b>	Katie Hayes Tadd Hellwig	
<b>Tennessee (3)</b>	Brandon Edgerson Jeanne Ezell Casey White	
<b>Texas (6)</b>	Lourdes Cuellar Dianne Fox Tricia Meyer Julie Nelson Lance Ray James Wilson	
<b>Utah (3)</b>	Travis Dick Leigh Fritz Krystal Moorman	
<b>Vermont (2)</b>	Kevin Marvin Jeffrey Schnoor	

<b>STATE</b>	<b>DELEGATES</b>	<b>ALTERNATES</b>
<b>Virginia (4)</b>	Emily Dyer Kelly Martin Eric Maroyka Rodney Stiltner	
<b>Washington, D.C. (2)</b>	Monique Bonhomme John Quinn	
<b>Washington State (4)</b>	Andrea Corona <sup>2</sup> Steven Riddle Terry Clark Roger Woolf	
<b>West Virginia (2)</b>	Justin Hare Carol Woodward	
<b>Wisconsin (4)</b>	Terry Audley Arlene Iglar <sup>1</sup> Ryan Miller Kate Schaafsma <sup>2</sup> Michelle Thoma	
<b>Wyoming (2)</b>	Linda Gore-Martin Kirsi Ludwig	
<b>SECTIONS AND FORUMS</b>	<b>DELEGATES</b>	
<b>Ambulatory Care Practitioners</b>	Melanie Dodd	
<b>Clinical Specialists and Scientists</b>	Christopher Betz	
<b>Inpatient Care Practitioners</b>	Daniel Degnan	
<b>Pharmacy Informatics and Technology</b>	Barbara Giacomelli	
<b>Pharmacy Practice Managers</b>	Thomas Kirschling	
<b>New Practitioners Forum</b>	Joshua Fleming	
<b>Pharmacy Student Forum</b>	Kristina Lantis	
<b>FRATERNAL</b>	<b>DELEGATES</b>	<b>ALTERNATES</b>
<b>U.S. Air Force</b>	LtCol.Winnie Lok-Park	
<b>U.S. Army</b>	LLTC Stacey Causey	
<b>U.S. Coast Guard</b>	Capt. Chae Chong	
<b>U.S. Navy</b>	CDR Angelica Klinski <sup>1</sup> LCDR Janel Rossetto <sup>2</sup>	
<b>U.S. Public Health Service</b>	Randy Seys	
<b>Veterans Affairs</b>		

**REPORT OF THE**  
**COMMITTEE ON RESOLUTIONS**

June 7, 2015

Denver, Colorado

Christene M. Jolowsky, Chair  
John A. Armitstead, Vice Chair  
Paul W. Bush  
Donald E. Letendre  
Gerald E. Meyer  
Kathleen S. Pawlicki  
Steve S. Rough  
Ranee M. Runnebaum  
Philip J. Schneider  
Kelly M. Smith  
James A. Trovato  
Paul W. Abramowitz, Secretary

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

Resolutions not voluntarily withdrawn by the submitter that meet the requirements of the governing documents shall be presented to the House of Delegates by the Committee on Resolutions at the first meeting and acted upon at the second meeting. They shall be submitted to delegates with one of the following recommendations: (a) recommend adoption, (b) do not recommend adoption, (c) recommend referral for further study, or (d) presented with no recommendation of the Committee on Resolutions.

Action by the House of Delegates shall be on the substance of the resolutions and not on the recommendation of the Committee on Resolutions.

Pursuant to the above article, the Committee on Resolutions presents the attached resolution to the House of Delegates. The recommendation of the Committee is to **refer the resolution to the appropriate ASHP committee or task force, as determined by the Board of Directors, for further study**. The Committee concluded that the legal and pharmacy practice issues addressed in the resolution are of such complexity that expert review would be required to provide the Board of Directors and House of Delegates with sufficient information to make an informed decision on ASHP professional policy. Among the issues identified by the Committee on Resolutions are the conflicts between federal drug laws and state medical marijuana laws and the consequential legal risks pharmacists could incur when managing medical marijuana, the inherent uncertainties of dosing a botanical or botanically derived product, and whether national accreditation or educational standards regarding medical marijuana could be developed in light of varying state laws and regulations that conflict with federal law. The Committee agreed that the issues presented by the resolution are very important but that there was a need for further study and expert consultation given the potentially far-reaching implications of the proposed changes in policy.

Delegates are reminded that the substance of the resolution is the amendment of existing ASHP policy 1101, Medical Marijuana, as described in the resolution. The options for House action on the resolution, to be taken at the second meeting, are to (a) approve the motion to amend the policy; (b) defeat the motion to amend the policy; (c) refer the motion for further study by a committee or task force to be determined by the Board of Directors (**the option recommended by the Committee on Resolutions**); or (d) amend the resolution, which would then require due consideration by the Board of Directors at its next meeting in September.

## **Resolution for 2015 ASHP House of Delegates: Pharmacist Oversight of Medical Marijuana Dispensaries**

**Submitted By:** Monique Bonhomme and Ikenna Unegbu

**Subject:** Pharmacist Oversight of Medical Marijuana Dispensaries

**Received:** March 8, 2015

**Motion:** To amend ASHP policy 1101, Medical Marijuana, to read as follows:

### **1101**

#### **MEDICAL MARIJUANA**

*Source: Council on Therapeutics*

To oppose state legislation that authorizes the use of medical marijuana until there is sufficient evidence to support its safety and effectiveness and a standardized product that would be subject to the same regulations as a prescription drug product; further,

To recognize that where medical marijuana is legal, pharmacists should apply their expertise in medication management and use to ensuring safe and effective use of medical marijuana; further,

To encourage research to further define the therapeutically active components, effectiveness, safety, and clinical use of medical marijuana; further,

To advocate for the development of processes that would ensure standardized formulations, potency, and quality of medical marijuana products to facilitate research; further,

To encourage the Drug Enforcement Administration to eliminate barriers to medical marijuana research, including review of medical marijuana's status as a Schedule I controlled substance, and its reclassification, if necessary to facilitate research; further,

To support state health department efforts to compile research on dosing of medical marijuana to provide guidance for healthcare providers; further,

To support the procurement, storage, preparation, or distribution of medical marijuana by licensed pharmacies or health care facilities for purposes other than research in states where medical marijuana is legal; further,

To support laws and regulations that would permit pharmacists to provide medication therapy management, track patient outcomes, and manage medications to optimize safety and efficacy at state-approved medical marijuana dispensaries; further,

To support, in states where medical marijuana is legal, mandatory continuing education that prepares pharmacists to respond to patient and clinician questions about the therapeutic and legal issues surrounding medical marijuana use; further,

To advocate for the creation of a national accreditation program for medical marijuana dispensaries that would require counseling of patients and certification of healthcare providers practicing in them; further,

To support efforts to develop national credentialing or certificate programs for pharmacists whose practices involve medical marijuana; further,

To oppose the smoking of marijuana in settings where smoking is prohibited.

(Note: As defined by the Congressional Research Service, the term *medical marijuana* refers to uses of botanical marijuana that qualify for a medical use exception under the laws of certain states and under the federal Investigational New Drug Compassionate Access Program. Botanical marijuana includes the whole or parts of the natural marijuana plant and therapeutic products derived therefrom, as opposed to drugs produced synthetically in the laboratory that replicate molecules found in the marijuana plant.)

**Background:** ASHP policy 1101, Medical Marijuana, would be amended as follows (underscore indicates new text, ~~striketrough~~ indicates deletions):

**1101**

**MEDICAL MARIJUANA**

*Source: Council on Therapeutics*

To oppose state legislation that authorizes the use of medical marijuana until there is sufficient evidence to support its safety and effectiveness and a standardized product that would be subject to the same regulations as a prescription drug product; further,

To recognize that where medical marijuana is legal, pharmacists should apply their expertise in medication management and use to ensuring safe and effective use of medical marijuana; further,

To encourage research to further define the therapeutically active components, effectiveness, safety, and clinical use of medical marijuana; further,

To advocate for the development of processes that would ensure standardized formulations, potency, and quality of medical marijuana products to facilitate research; further,

To encourage the Drug Enforcement Administration to eliminate barriers to medical marijuana research, including review of medical marijuana's status as a Schedule I controlled substance, and its reclassification, if necessary to facilitate research; further,

To support state health department efforts to compile research on dosing of medical marijuana to provide guidance for healthcare providers; further,

To ~~oppose~~ support the procurement, storage, preparation, or distribution of medical marijuana by licensed pharmacies or health care facilities for purposes other than research in states where medical marijuana is legal; further,

To support laws and regulations that would permit pharmacists to provide medication therapy management, track patient outcomes, and manage medications to optimize safety and efficacy at state-approved medical marijuana dispensaries; further,

To ~~encourage~~ support, in states where medical marijuana is legal, mandatory continuing education that prepares pharmacists to respond to patient and clinician questions about the therapeutic and legal issues surrounding medical marijuana use; further,

To advocate for the creation of a national accreditation program for medical marijuana dispensaries that would require counseling of patients and certification of healthcare providers practicing in them; further,

To support efforts to develop national credentialing or certificate programs for pharmacists whose practices involve medical marijuana; further,

To oppose the smoking of marijuana in settings where smoking is prohibited.

(Note: As defined by the Congressional Research Service, the term *medical marijuana* refers to uses of botanical marijuana that qualify for a medical use exception under the laws of certain states and under the federal Investigational New Drug Compassionate Access Program. Botanical marijuana includes the whole or parts of the natural marijuana plant and therapeutic products derived therefrom, as opposed to drugs produced synthetically in the laboratory that replicate molecules found in the marijuana plant.)

Medical cannabis or medical marijuana refers to the use of cannabis and its constituent cannabinoids, such as tetrahydrocannabinol (THC) and cannabidiol (CBD), as medical therapy to treat disease and alleviate symptoms.

On December 16, 2014, Congress ended the federal prohibition on medical marijuana. A number of states and the District of Columbia have legalized medical marijuana under different provisions. For example, per the D.C. Department of Health, the Medical Marijuana Program states:

All qualifying patients have the right to obtain and use marijuana for medical purposes when his or her primary physician has provided a written recommendation that bears his or her signature and license number. This recommendation must assert that the use of marijuana is medically necessary for the patient for the treatment of a qualifying medical condition or to mitigate the side effects of a qualifying medical treatment.

The FDA has not approved medical cannabis in any form for any indication. Marijuana is currently a Schedule I controlled substance, as defined by the United States Controlled Substances Act based on three criteria: 1) the drug or other substance has a high potential for abuse; 2) the drug or other substance has no currently accepted medical use in treatment in the United States; and 3) there is a lack of accepted safety for use of the drug or other substance under medical supervision.

However, there are companies working toward getting FDA approval for cannabis-based medicines and for the treatment of post-traumatic syndrome disorder. They desire to have medical cannabis approved by the FDA so anyone, regardless of state of residence, will have access to the medicine. The Controlled Substances Act provides a process for rescheduling controlled substances by petitioning the Drug Enforcement Administration.

The FDA has approved two oral cannabinoids for use as medicine: dronabinol and nabilone. Both have been approved as an antiemetic for cancer chemotherapy-induced nausea and vomiting that has failed to respond adequately to conventional therapy. Dronabinol, a synthetic THC, is listed as Schedule III and has also been approved for anorexia associated with AIDS-related weight loss. Nabilone, a synthetic cannabinoid, is listed as Schedule II. Nabiximols, an oromucosal spray derived from two strains of *Cannabis sativa* and containing THC and CBD, is not approved in the United States but is approved in several European countries, Canada, and New Zealand as of 2013 for limited treatment for spasticity and neuropathic pain associated with multiple sclerosis and intractable cancer pain when other treatments have failed to work.

In Connecticut, regulations promulgated in May 2012 require that medical marijuana, which may be used to treat a limited list of qualifying ailments, be dispensed under the supervision of pharmacists. Qualifying ailments include cancer, glaucoma, HIV or AIDS, Parkinson's, multiple sclerosis, damage to the nervous tissue in the spinal cord, intractable spasticity, epilepsy, cachexia, wasting syndrome, Crohn's disease, or post-traumatic stress disorder. Connecticut is the first state to require that pharmacists be on site to oversee and staff state-approved medical marijuana dispensaries. Nick Tamborrino, a pharmacist who used to work at the Yale-New Haven Health System, has been approved to open a medical marijuana dispensary. He plans to collect data for the Canadian Consortium for the Investigation of Cannabinoids as part of his research.

Minnesota is the 22nd medical marijuana state but only the second state to involve pharmacists in dispensing medical cannabis. The pharmacist will be employed by the drug manufacturer and will help patients determine the appropriate dosage. However, healthcare

providers are not required to participate in the process used to certify that patients have a medical condition that qualifies for treatment with medical marijuana.

In Illinois, medical marijuana is under a 4-year pilot program. Joseph Friedman, a pharmacist, was granted a permit to sell and grow medical marijuana in Illinois. He wants to create a pharmacy model with a pharmacist in charge and employees counseling patients on what particular marijuana strain would be best for them. He would also like to expand and have pharmacy students rotate in and out of the dispensary.

Medical marijuana can interact with a number of drugs, including barbiturates, central nervous system depressants, protease inhibitors, selective serotonin reuptake inhibitors, tricyclic antidepressants, and anticholinergics, among others. There are also special populations to consider, including but not limited to pregnant, immunocompromised, and obese patients.

State health departments plan to compile research published to date to give pharmacists some general guidance on dosing in order to help determine a formal guideline in the future. It is imperative to recognize that as the evidence for the safety and effectiveness of medical marijuana in the treatment of certain medical conditions mounts, ASHP opposition to state legislation that authorizes its use for those conditions will need to be reviewed.

The National Association of Cannabis Pharmacy was launched in 2014. Its purpose is to support pharmacists who dispense, administer, and compound cannabis-based products to treat specialty diseases. They also support the development of advanced training of pharmacists in order to lead patient education and treatment plans.

**Outcome:** To allow pharmacists to have an expanded role in the dispensing and regulation of medical marijuana. Advanced training and certification should be required for all dispensaries and mandatory counseling of medical marijuana patients in all jurisdictions and states, including the District of Columbia.



# House of Delegates

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## **HOUSE OF DELEGATES**

### **REPORT OF THE**

### **COMMITTEE ON NOMINATIONS**

June 7, 2015

Denver, Colorado

Rob Adamson (Chair), New Jersey  
Christene Jolowsky (Vice Chair), Minnesota  
Jill Bates, North Carolina  
Leigh Briscoe-Dwyer, New York  
Erin Fox, Utah  
Jamie Sinclair, Minnesota  
Donna Soflin, Nebraska

## ASHP COMMITTEE ON NOMINATIONS

Mister Chair, Fellow Delegates:

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

Selection of nominees for Society office involves a series of challenging decisions on the part of the Committee. Ultimately, those decisions are intended to permit the membership to select leaders with the professional, intellectual, and personal qualities of leadership that will sustain the dynamism and pioneering spirit that have characterized both ASHP and health-system pharmacy practice.

First, the Committee must determine that a prospective nominee for office is an active member as required in the Charter. This is generally the easiest and most straightforward part of the Committee's work. The Committee must ascertain that each prospective nominee can perform the duties required of the office or offices to which he or she has been nominated. All nominees must be able to perform the duties of a Director, set forth in section 5.4 of the Bylaws. Presidential nominees must also be able to perform the duties of that office, set forth in article 4 of the Bylaws, and nominees for Chair of the House of Delegates must also be able to perform the special duties set forth in article 7 of the Bylaws.

The more difficult part of the Committee's work is to assess those intangible qualities of leadership, vision, engagement, and professional awareness that characterize the standout candidates – those truly able to provide leadership for ASHP and the profession. The Committee assesses the attributes of prospective candidates for office in areas such as:

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

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

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

The Committee's year-long process of receiving nominations and screening candidates is designed to

solicit extensive membership input and, ultimately, to permit the Committee to candidly and confidentially assess which candidates best fit the Society's needs. The Committee has met twice in person since the last session of the House of Delegates: on December 9, 2014, at the Midyear Clinical Meeting in Anaheim, California; and on April 16, 2015, at ASHP headquarters; and met once via teleconference. Review of nominees' materials was conducted continuously between March and April 2015 solely via secure electronic transmissions. This process has been reviewed for quality improvement and will be repeated for the 2015–2016 nomination cycle.

As in the past, the Committee used various means to canvass ASHP members and state affiliates for candidates who they felt were most qualified to lead us. All members were invited via announcements in the ASHP *Intersections*, online ASHP NewsLink bulletins, and the ASHP website to submit nominations for the Committee's consideration. Nominations from state affiliate societies were solicited through special mailings and the "state affiliate" edition of the online NewsLink service. At the 2014 Midyear Clinical Meeting, the Chair and Secretary made themselves available to receive nominations personally in a location and at a time that were publicized in ASHP news publications and correspondence.

Based upon recommendations from membership, state affiliates, and ASHP staff, the Committee contacted over 300 individuals identified as possible candidates. Some individuals were invited to accept consideration for more than one office. Of the nominees who responded to the invitation to place themselves in nomination, the breakdown by office is as follows:

PRESIDENT-ELECT: 5 accepted

BOARD OF DIRECTORS: 21 accepted

CHAIR, HOUSE OF DELEGATES: 7 accepted

A list of candidates that were slated was provided to delegates following the Committee's meeting on April 16, 2015.

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

#### **President-Elect**

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

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

#### **Board of Directors**

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

Seena L. Haines, Pharm.D., BCACP, FASHP, BC-ADM, CDE, FAPhA (West Palm Beach, FL)

Todd A. Karpinski, Pharm.D., M.S., FASHP (Menomonee Falls, WI)

Jennifer M. Schultz, Pharm.D., FASHP (Bozeman, MT)

#### **Chair, House of Delegates**

Amber J. Lucas, Pharm.D., BCPS, FASHP (Olathe, KS)

Natasha C. Nicol, Pharm.D., FASHP (Pawleys Island, SC)

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

**PRESIDENT-ELECT**

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

Gersema has focused her career to advance a decentralized and integrated pharmacy practice model emphasizing accountability, collaboration, and team-based care.

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

**JAMES A. TROVATO, Pharm.D., M.B.A., BCOP, FASHP** (410-706-2751; [jtrovato@rx.umaryland.edu](mailto:jtrovato@rx.umaryland.edu)) is Associate Professor and oncology specialist at the University of Maryland School of Pharmacy in Baltimore. Trovato completed a B.S. in pharmacy from the Massachusetts College of Pharmacy, Pharm.D. degree from Purdue University, and an ASHP-accredited oncology residency at the University of Texas Health Science Center at San Antonio. Trovato is a leader in oncology pharmacy practice, professional education, and residency training. He has developed and implemented an innovative collaborative drug therapy management service with the Medical Oncology Hematology community practice at the University of Maryland Baltimore Washington Medical Center. He is Past President of the Maryland Society of Health-System Pharmacists. Trovato has served ASHP as Chair, House of Delegates; Chair and Director-at-Large, Executive Committee of the Section of Clinical Specialists and Scientists; Chair, Council on Educational Affairs; multi-year ASHP Delegate; Faculty Liaison; and advisor to the ASHP student chapter.

**BOARD OF DIRECTORS**

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

Cowan serves as Director of Pharmacy at Angel Medical Center, a critical access hospital, which is part of the Mission Health System in North Carolina. She has been a small and rural hospital pharmacist for 35 years with 27 of those years spent as director.

Cowan is a long-time member of ASHP with experience on many committees, councils, and workgroups including chairmanship of the Section of Inpatient Care Practitioners (SICP) Executive Committee, Small and Rural Hospital advisory group, and SICP Committee on Nominations.

**SEENA L. HAINES, Pharm.D., FASHP, FAPhA, BCACP, BC-ADM, CDE** (561-803-2713; [seenahaines@pba.edu](mailto:seenahaines@pba.edu)) is Professor and Associate Dean at Palm Beach Atlantic University's School of Pharmacy. Haines developed a replicable medication therapy management model that resulted in the founding of four pharmacist-based clinics in Palm Beach County. The Integrated Pharmacotherapy Services™ clinics received DSME ADA recognition as a single-provider/multi-site program and over \$750,000 in grant funding to provide pharmacist-directed primary care. Haines established PBA's pharmacy practice residency. She served as Chair and Director-at-Large for the Section of Ambulatory Care Practitioners. She is Board Certified in Ambulatory Care Practice (BCACP), received the AACP Innovation in Teaching Award 2010, was Chair for the ASHP SAG on Reimbursement for Cognitive Services, was inaugural AACP Self-Care SIG Chair, is a Certified Diabetes Educator who is Board Certified in Advanced Diabetes Management (BC-ADM), was the 2009 Preceptor of Distinction, the 2008 Hero in Medicine, and was the inaugural AACP Academic Leaders Fellow.

**BOARD OF DIRECTORS (continued)**

**TODD KARPINSKI, Pharm.D., M.S., FASHP** (414-777-3583; [todd.karpinski@froedtert.com](mailto:todd.karpinski@froedtert.com)) is Chief Pharmacy Officer at Froedtert & The Medical College of Wisconsin. Karpinski is responsible for all operational, clinical, financial, ambulatory, and retail operations for 3 acute care hospitals and over 300 primary and specialty clinics across the greater Milwaukee area.

Karpinski received his Doctor of Pharmacy from Drake University and Master of Science in Hospital Pharmacy from the University of Kansas. He completed an ASHP-accredited pharmacy practice management residency at Kansas University Hospital. Over the past 15 years he has held pharmacy leadership positions in both academic and community hospital settings.

Karpinski has been very active in pharmacy organizations at the national, state, and local level. He is currently the Immediate Past Chair for the Section of Pharmacy Practice Managers within ASHP, Chair of the Business of Pharmacy Enterprise within UHC, member of the PPMI Advisory Board for PSW, and Past President of ICHP.

**JENNIFER M. SCHULTZ, Pharm.D., FASHP** (406-414-5393; [jschultz@bdh-boz.com](mailto:jschultz@bdh-boz.com)), is Clinical Pharmacy Supervisor/Residency Program Director at Bozeman Deaconess Health Services in Bozeman, Montana, where she provides direct patient care, precepts residents/students, and strives to enhance medication outcomes.

Schultz received her Pharm.D. degree from Creighton University and completed an ASHP-accredited pharmacy residency at Group Health Cooperative of Puget Sound. She participated in ASHP Foundation's Pharmacy Leadership Institute in 2014.

Schultz has been an active member of ASHP, serving the Section of Inpatient Care Practitioners (SICP) Executive Committee as Chair and Director-at-Large. She has served as Chair for the Pharmacy Technician Statement Committee, the Joint Section/Forum PPMI Coordinating Committee, the Council on Education and Workforce Development, and the Task Force for Pharmacy's Changing Demographics. She has served as Program Chair for Midyear Clinical Meeting programs, state delegate, and has published in AJHP. Schultz was honored with the Distinguished Service Award from SICP in 2014.

**CHAIR, HOUSE OF DELEGATES**

**AMBER J. LUCAS, Pharm.D., BCPS, FASHP** (913-791-4287; [amber.lucas@olathehealth.org](mailto:amber.lucas@olathehealth.org)) is a Clinical Pharmacist at Olathe Medical Center in Olathe, Kansas specializing in obstetrics and neonatology. Amber received her Pharm.D. from the University of Kansas and completed a PGY1 residency at the Nebraska Medical Center. She is pursuing an M.B.A. in Healthcare Management through New England College. Amber has published and presented on pharmacy clinical and leadership topics including policy, scope of practice, communication strategies, neonatal medication safety, and the practice model.

Amber has served ASHP and the House of Delegates extensively as past Chair of the Council on Public Policy and FASHP Recognition Committee, as a Kansas Delegate, on the Committee on Nominations, and as a national judge for the Clinical Skills Competition. She is Vice-Chair of the Clinical Leadership SAG for the SCSS. She is a past President of the Kansas Council of Health-System Pharmacists, a Fellow of ASHP and was honored as KCHP Pharmacist of the Year.

Dr. Lucas's statement:

*Now is a time of great opportunity for our profession. Healthcare reform is focusing on the things that we do well. Quality and safety are being measured, total costs of care are being scrutinized, and a more holistic approach to population health and managing the continuum of care is valued. These are areas where we as pharmacists must take the lead for our patients!*

*This convergence of value being measured, and our ability to provide it has presented tremendous opportunity for our profession if we seize it now. ASHP's aims of achieving provider status and expanding ambulatory practice will help us improve population health and transitions of care.*

*The ASHP policy process and the House of Delegates are critical to moving the profession toward these goals. Through thoughtful deliberation and advocacy, we have shaped our profession into what it is today. This process guides us in the care of our patients and drives the future of our profession and our practice.*

*I am humbled and honored by this nomination and the potential opportunity to serve as Chair of the ASHP House of Delegates; a position which listens to your voices and guides the strategic vision of our organization and our profession.*

**CHAIR, HOUSE OF DELEGATES (continued)**

**NATASHA C. NICOL, Pharm.D., FASHP** (843-318-2027; [natasha.nicol@cardinalhealth.com](mailto:natasha.nicol@cardinalhealth.com)) is Director, Global Patient Safety Affairs for Cardinal Health, Inc.

She received her doctorate of pharmacy degree from the University of Maryland School of Pharmacy. She is faculty for the Institute for Healthcare Communication, a certified Just Culture trainer, TeamSTEPPS Master Trainer, and visiting professor for the South Carolina and Presbyterian Colleges of Pharmacy.

She is a Champion for the World Health Organization's World Alliance for Patient Safety, and past-President of the South Carolina Society of Health-System Pharmacists. She is a Fellow of the American Society of Health-System Pharmacists and served on the Council on Education and Workforce Development, as well as the House of Delegates. She was the Program Chair for the ASHP Medication Safety Collaborative. She was recognized for her work as Director of Pharmacy at McLeod Health with the ASHP Award for Excellence in Medication-Use Safety and was named Pharmacist and Mentor of the Year by SCSHP.

She is a frequent presenter to professional groups, primarily focusing on medication safety as it relates to culture, use of technology and development of processes.

Dr. Nicol's statement:

*"Things do not happen. Things are made to happen."*

*- John F Kennedy*

*This statement embodies the ASHP House of Delegates: a committed, dedicated group working to shape and position our profession and its future. We are on the cusp of a great turning point in our unprecedented legislative efforts to secure provider status for pharmacists. Not only will this bring us to the forefront in the healthcare leadership spectrum, it will open new doors to advancing practice.*

*I will challenge the House to develop policy to anticipate the effects, on our profession, of the many changes occurring in healthcare. We must be the ones proposing the changes, as opposed to reacting to the proposals of others. We must proactively engage and work to influence all government and regulatory bodies to ensure pharmacists are active participants in policy development.*

*ASHP is a uniquely positioned organization with a phenomenal group of volunteers who selflessly and tirelessly engage in creative and courageous efforts to ensure pharmacists remain at the forefront of issues involving patient care. We must define our future for ourselves and our patients and not allow the future to define us.*

*I am honored to receive this nomination. It would truly be a privilege to serve as the Chair of the House of Delegates and lead an exceptional collaboration of advocates whose work in policy, communications and patient safety is for the betterment of those we serve. But, we can only do this with strong leadership and by making things happen.*



pharmacists advancing healthcare

# House of Delegates

## Final 2015 Policy Recommendations

### Council on Public Policy

1. Pharmacist Participation in Health Policy Development
2. Pharmacist Recognition as a Healthcare Provider
3. Pharmaceutical Product and Supply Chain Integrity
4. Patient Adherence Programs as Part of Health Insurance Coverage
5. Statutory Protection for Medication-Error Reporting
6. Premarketing Comparative Clinical Studies
7. Funding, Expertise, and Oversight of State Boards of Pharmacy
8. Support for FDA Expanded Access (Compassionate Use) Program
9. Approval of Biosimilar Medications

### Council on Therapeutics

1. Naloxone Availability
2. Complementary and Alternative Medicine in Patient Care
3. Development of Abuse-Resistant Narcotics
4. Quality Patient Medication Information
5. Safety and Effectiveness of Ethanol Treatment for Alcohol Withdrawal Syndrome
6. Research on Drug Use in Obese Patients
7. Chemotherapy Parity
8. Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship

### Council on Education and Workforce Development

1. Developing Leadership Competencies
2. Pharmacy Technician Training and Certification

### Council on Pharmacy Management

1. Impact of Insurance Coverage Design on Patient Care Decision
2. Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs
3. Disposition of Illicit Substances
4. Pharmacist's Role in Population Health Management
5. ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

### Council on Pharmacy Practice

1. Support for the Second Victim of Medical Errors
2. Standardization of Doses
3. Prescription Drug Abuse
4. Pharmacist's Role in Urgent and Emergency Situations
5. Excipients in Drug Products
6. Online Pharmacy and Internet Prescribing
7. Standardization of Small-Bore Connectors To Avoid Wrong-Route Errors
8. Medication Safety Officers Role
9. Pharmacist Participation in Capital Punishment
10. ASHP Statement on Pharmacist's Role in Substance Abuse, Prevention, Education and Assistance

### Section of Pharmacy Informatics and Technology

ASHP Statement on the Pharmacist's Role in Clinical Informatics

**Board of Directors Reports on Councils.** ASHP councils met in person in September 2014 and again by teleconference in February 2015; the Council on Pharmacy Practice also met by teleconference in April 2015. Each report has three sections: Policy Recommendations (new policies initiated by the council, approved by the Board of Directors, and subject to ratification by the House of Delegates); Board Actions (Board of Directors consideration of council recommendations that did not result in new policies, and actions by the Board in areas for which it has final authority); and Other Council Activity (additional subjects the council discussed, including issues for which it has begun to develop policy recommendations). The House will consider an additional recommendation initiated by the Section of Pharmacy Informatics and Technology and approved by the Board of Directors.



pharmacists advancing healthcare

# House of Delegates

## Board of Directors Report on the Council on Public Policy (Final)

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

*Kathy Pawlicki, Board Liaison*

### Council Members

- John Hertig, *Chair* (Indiana)
- John Pastor, *Vice Chair* (Minnesota)
- Joe Anderson (New Mexico)
- Leigh Briscoe-Dwyer (New York)
- Angela Darr (South Dakota)
- Carla Frye (Illinois)
- Tracy Hagemann (Oklahoma)
- Darrell Machir (Florida)
- Scott Meyers (Illinois)
- Gloria Sachdev (Indiana)
- Maria Serpa (California)
- Darrell Machir, *New Practitioner* (Maryland)
- Angela Skaff, *Student* (Florida)
- Brian Meyer, *Secretary*

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## Policy Recommendations

### 1

### Pharmacist Participation in Health Policy Development

- 1 To urge pharmacists to participate with policymakers and stakeholders in the
- 2 development of medication-related health policies at the national, state, and
- 3 community levels; further,
- 4 To develop tools and resources to assist pharmacists in fully participating in health
- 5 policy development at all levels.

#### **Rationale**

Health policy developed at the federal, state, and local levels increasingly impacts medication use, particularly as payment and delivery models require the interprofessional healthcare team to collaboratively deliver care to meet quality and outcomes measures. The perspective of pharmacists practicing in hospital and ambulatory care settings is essential to the development of health policy. At the federal level, policy development includes drug development, distribution, and control; coverage for medication therapy; interoperability of health information; and all aspects of patient safety. Those federal issues also exist at the state and local level, but also include the full range of scope of practice issues.

The absence of hospital and ambulatory care pharmacist input into health policy development leads to suboptimal public policy, inefficient use of resources (public and private), and the potential for suboptimal patient care at the individual patient level and with specific patient populations. Furthermore, poorly developed public policy results in pharmacists being unable to practice at the top of their licenses.

#### **Background**

The Council reviewed the consensus recommendations of the Ambulatory Conference and Summit, noting that the recommendations were not ASHP policy but did represent the consensus at the conference held in March 2014. The Council also reviewed a number of relevant ASHP policies within its purview that corresponded to the consensus recommendations. The Council was particularly interested in consensus recommendation 2.3 as it related to population health:

Pharmacists who provide ambulatory care services must leverage health information technologies to efficiently identify populations of patients for whom evidence based, comprehensive medication management is indicated.

Council discussion concerning this consensus recommendation centered on engagement on the issues of population health and the use of information technology. The discussion evolved to the broader notion of engagement in health policy at all levels. The Council felt that a separate policy was needed that addressed the imperative for pharmacists in practicing in hospital and ambulatory care settings to be engaged in health policy development. It also noted that addressing population health should also be considered in other ASHP policies and noted the example of the establishment and influence of accountable care organizations (ACOs) and patient-centered medical homes (PCMHs). The Council also acknowledged the policy recommendation by the Council on Pharmacy Management concerning the Pharmacist's Role in Population Management. The policy recommendation incorporates much of the discussion about the current importance surrounding population health management.

In discussing other available actions, the Council recommended that quality measures be developed to inform members and be included in a toolkit to develop and enhance their practices. Other actions included surveys of practice sites to understand the best practices and innovations that can be adopted by members practicing in ambulatory care.

## 2

### Pharmacist Recognition as a Healthcare Provider

- 1 To advocate for changes in federal (e.g., Social Security Act), state, and third-party
- 2 payment programs to define pharmacists as healthcare providers; further,
  
- 3 To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-
- 4 quality care that is cost effective, resulting in improved patient outcomes; further,
  
- 5 To recognize that pharmacists, as healthcare providers, improve access to patient care
- 6 and bridge existing gaps in healthcare; further,
  
- 7 To collaborate with key stakeholders to describe the covered direct patient-care
- 8 services provided by pharmacists; further,
  
- 9 To advocate for compensation for pharmacist services by any available payment
- 10 program.

(Note: This policy would supersede ASHP policy 1307.)

#### **Rationale**

Recognition of pharmacists as healthcare providers is emerging and being codified in state law as well as in current federal legislative proposals (e.g., H.R. 4190). In some cases this recognition also includes specified compensation through existing payment mechanisms (e.g., federal Medicare Part B or state Medicaid programs). With recognition, pharmacists should be compensated for their patient-care services by all public and private payers.

**Background**

The Council voted to recommend amending policy 1307 as follows (underline indicates new text, ~~striketrough~~ indicates deletions):

To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as health care providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as health care providers, improve access to patient care and bridge existing gaps in health care; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

~~To pursue a standard mechanism for compensating pharmacists who provide these services.~~

To advocate for compensation for pharmacist services by any available payment program.

The Council reviewed activity at the state level to recognize pharmacists as providers in state practice acts, state insurance codes, and the Medicaid program. It also reviewed ASHP policy 1307 and noted that it provided for advocacy at the state level through ASHP's state affiliates. The Council recognized the variability in state law and agreed to develop a document to assist affiliates in defining terms that are used in conjunction with this topic. Such terms include *provider status*, *advanced practice pharmacist*, *pharmacist clinician*, as well as *dependent* and *independent prescribing*. In addition, the Council recommended that model language incorporating these definitions be developed in conjunction with the National Association of Boards of Pharmacy.

## 3

## Pharmaceutical Product and Supply Chain Integrity

- 1 To encourage the Food and Drug Administration (FDA) and relevant state authorities to
- 2 take the steps necessary to ensure that (1) all drug products entering the supply chain
- 3 are thoroughly inspected and tested to establish that they have not been adulterated
- 4 or misbranded and (2) patients will not receive improperly labeled and packaged,
- 5 deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,
  
- 6 To encourage FDA and relevant state authorities to develop and implement regulations
- 7 to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and
- 8 manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure
- 9 accurate documentation at any point in the distribution chain of the original source of
- 10 drug products and chain of custody from the manufacturer to the pharmacy; further,
  
- 11 To advocate for the establishment of meaningful penalties for companies that violate
- 12 current good manufacturing practices (cGMPs) intended to ensure the quality, identity,
- 13 strength, and purity of their marketed drug product(s) and raw materials; further,
  
- 14 To advocate that drug product labeling include a readily available means to retrieve the
- 15 location of the facility that manufactured the specific lot of the product; further,
  
- 16 To advocate that this readily retrievable manufacturing information be available
- 17 prospectively to aid purchasers in determining the quality of a drug product; further,
  
- 18 To urge Congress and state legislatures to provide adequate funding, or authority to
- 19 impose user fees, to accomplish these objectives.

(Note: This policy would supersede ASHP policy 0907.)

### **Rationale**

The aspect of drug product selection that is not transparent from the labeling is its quality. This information needs to be readily available so those who make the purchasing decision on behalf of hospitals and health systems can factor quality into the decision. One aspect of quality is the production and compliance history of a manufacturer and the specific location of the manufacturing plant. This information has been useful in responding to a recall, but it is also important as part of the procurement process. The FDA's [Strategic Plan for Preventing and Mitigating Drug Shortages](#) recommends that purchasers of medications consider quality as a component of the purchasing decision. FDA publishes some quality information about manufacturers but in subcontracting and licensing situations, it is not always known who the actual manufacturer is and which specific plant location produced the product.

**Background**

The Council voted to recommend amending policy 0907 as follows (underscore indicates new text, ~~striketrough~~ indicates deletions):

To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate that drug product labeling include a readily available means to retrieve the location of the facility that manufactured the specific lot of the product; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

The Council considered a Delegate recommendation to develop policy that would provide more transparency about a drug product as manufacturer and specific plant location. The Council agreed that more transparency would aid purchasers in evaluating drug products and enable quality to be factored into a purchase decision. It noted that including quality into these decisions might help mitigate drug shortages since higher quality should be associated with production facilities that experience fewer compliance issues and down time. The Council revised policy 0907 to include two new clauses advocating for this transparency about specific manufacturer and plant location.

## 4

## Patient Adherence Programs as Part of Health Insurance Coverage

- 1 To advocate for the pharmacist's role in patient medication adherence programs that
- 2 are part of health insurance plans; further,
- 3 To advocate those programs that (1) maintain the direct patient–pharmacist
- 4 relationship; (2) are based on the pharmacist's knowledge of the patient's medical
- 5 history, indication for the prescribed medication, and expected therapeutic outcome;
- 6 (3) use a communication method desired by the patient; (4) are consistent with federal
- 7 and state regulations for patient confidentiality; and (5) permit dispensing of partial fills
- 8 or overfills of prescription medications in order to synchronize medication refills and aid
- 9 in medication adherence.

(Note: This policy would supersede ASHP policy 0116.)

### **Rationale**

Current payment rules for Medicare Part D plans require a prorated cost-sharing rate for prescriptions dispensed with less than a 30-day supply. This is allowed to avoid waste in the event that a prescription is modified in response to an adverse reaction. Aligning or synchronizing a medication to all of a patient's chronic medications has been proven to improve adherence. Although Medicare has adopted a policy allowing for a daily cost-sharing rate, other payers have not followed suit. ASHP advocates for similar changes in state law and regulation, since such a change would allow for broader synchronization and improved adherence for patients covered by Medicaid and private third-party payers.

### **Background**

The Council voted to recommend amending policy 0116 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To ~~support~~ advocate for the pharmacist's role in patient medication adherence programs that are part of health insurance plans; further,

To ~~support~~ advocate those programs that (1) maintain the direct patient–pharmacist relationship; (2) are based on the pharmacist's knowledge of the patient's medical history, indication for the prescribed medication, and expected therapeutic outcome; (3) use a communication method desired by the patient; (4) are consistent with federal and state regulations for patient confidentiality; and (5) ~~are consistent with ASHP policy on confidentiality of patient health care information.~~ permit dispensing of partial fills or overfills of prescription medications in order to synchronize medication refills and aid in medication adherence.

The Council discussed the need for advocacy at the state level to permit daily cost sharing for partial fill or overfill of prescriptions for the purpose of aligning or synchronizing a patient's chronic medications. The Council revised policy 0116 to include advocacy at the state level to permit medication synchronization programs by state and third party payers.

## 5

### Statutory Protection for Medication-Error Reporting

- 1 To collaborate with other healthcare providers, professions, and stakeholders to
- 2 advocate and support state and federal legislative and regulatory initiatives that
- 3 provide liability protection for the reporting of actual and potential medication errors
- 4 by individuals and healthcare providers; further,
  
- 5 To seek state and federal liability protection for medication-error reporting that is
- 6 similar in concept to that which applies to reporting safety incidents and accidents in
- 7 the aviation industry.

(Note: This policy would supersede ASHP policy 0011.)

#### **Rationale**

Medication-error reporting at the state and federal level has been shown to improve medication-use systems and aid in conducting a root cause analysis of a medication error. Liability protection for such reporting at the federal and state level is necessary to achieve this analysis and improve patient safety. Both state and federal liability protection is needed, since legal actions can be initiated in state courts as well as with the federal judiciary.

#### **Background**

The Council voted to recommend amending ASHP policy 0011 as follows (underscore indicates new text, ~~strike through~~ indicates deletions):

To collaborate with other healthcare providers, professions, and stakeholders to advocate and support state and federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and healthcare providers; further,

To seek state and federal liability protection for medication-error reporting that is similar in concept to that which applies to reporting safety incidents and accidents in the aviation industry.

As part of its sunset review, the Council discussed revising policy 0011 to include liability protection at the state level as well. Although the additions are limited to including state protection, Council members felt strongly that this inclusion was important.

## 6

## Premarketing Comparative Clinical Studies

- 1 To advocate that the Food and Drug Administration have the flexibility to decrease the
- 2 requirement for placebo-controlled studies and correspondingly impose a requirement
- 3 for comparative clinical trials.

(Note: This policy would supersede ASHP policy 0514.)

### **Rationale**

With the cost of drug development and approval increasing, the need for comparative clinical trials also is rising. The need for placebo-controlled studies is not always necessary when a product is in the same drug class (i.e., is a “me-too” drug). More generally, the flexibility for FDA to require placebo studies should be afforded where appropriate, whether or not a product is already approved in the same drug class.

### **Background**

The Council voted to recommend amending ASHP policy 0514 as follows (underscore indicates new text, ~~strike through~~ indicates deletions):

To advocate that the Food and Drug Administration (~~FDA~~) have the flexibility to decrease the requirement for placebo-controlled studies, and correspondingly impose a requirement for comparative clinical trials ~~as more new drug applications are filed for products in the same drug class.~~

As part of its sunset review of policies, the Council discussed revising policy 0514 to reflect the view that FDA should have the flexibility in requiring placebo controlled studies. Members felt that there are some situations where these studies are not appropriate and instead comparative studies would better serve the needs of the public.

## 7

## Funding, Expertise, and Oversight of State Boards of Pharmacy

- 1 To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply
- 2 chain through coordination and cooperation of state boards of pharmacy and other
- 3 state and federal agencies whose mission it is to protect the public health; further,
  
- 4 To advocate adequate representation on state boards of pharmacy and related
- 5 agencies by pharmacists who are knowledgeable about all areas of pharmacy practice
- 6 (e.g., hospitals, health systems, clinics, and nontraditional settings) to ensure
- 7 appropriate oversight; further,
  
- 8 To advocate for dedicated funds for the exclusive use by state boards of pharmacy and
- 9 related agencies including funding for the training of state board of pharmacy
- 10 inspectors and the implementation of adequate inspection schedules to ensure the
- 11 effective oversight and regulation of pharmacy practice, the integrity of the
- 12 pharmaceutical supply chain, and protection of the public; further,
  
- 13 To advocate that inspections be performed only by pharmacists competent about the
- 14 applicable area of practice.

(Note: This policy would supersede ASHP policy 0518.)

### **Rationale**

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

### **Background**

The Council voted to recommend amending ASHP policy 0518 as follows (underscore indicates new text, ~~strike through~~ indicates deletions):

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

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

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

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

In its sunset review, the Council revised policy 0518 to reflect recent experiences between state and federal jurisdiction as well as the funding needs of state boards to adequately carry out their missions. The Council felt strongly that the policy revisions needed to address the need for coordination with other state and federal agencies. It also felt that ASHP and its state affiliates should advocate for representation on state boards by pharmacists practicing in hospitals and health systems as well as other areas of pharmacy practice. Council members felt strongly that the policy should advocate for a dedicated stream of revenue for state boards in order to develop and train pharmacists as exclusive inspectors to ensure the protection of the public health.

## 8

### Support for FDA Expanded Access (Compassionate Use) Program

- 1 To advocate that the Food and Drug Administration (FDA) Expanded Access
- 2 (Compassionate Use) Program be the sole mechanism for patient access to drugs for
- 3 which an investigational new drug application (IND) has been filed, in order to preserve
- 4 the integrity of the drug approval process and assure patient safety; further,
- 5 To advocate for broader patient access to such drugs under the FDA Expanded Access
- 6 Program; further,
- 7 To advocate that IND applicants expedite review and release of drugs for patients who
- 8 qualify for the program; further,
- 9 To advocate that the drug therapy be recommended by a physician and reviewed and
- 10 monitored by a pharmacist to assure safe patient care; further,
- 11 To advocate for the patient's right to be informed of the potential benefits and risks via
- 12 an informed consent process, and the responsibility of an institutional review board to
- 13 review and approve the informed consent and the drug therapy protocol.

**Rationale**

Patient access to drugs for which an investigational new drug application (IND) has been filed is made available on a limited basis to individual patients under a compassionate-use program regulated by the FDA. With information about clinical trials and drugs under development readily available to patients, there is an increased demand for access to these therapies. In addition, three states have passed laws to permit patients who have exhausted approved drugs and treatment to have access to these potentially lifesaving drugs. Other states may follow suit in the future, and the FDA [has begun to respond](#) to this growing patient demand by streamlining its application process for individual patient expanded access. In order to respond to state legislative proposals, ASHP advocates preserving the integrity of drug development through strengthening the evidence-based clinical trial process and expanded patient access.

**Background**

The Council voted to recommend amending its September policy recommendation, Compassionate Use of Unapproved Experimental Drugs (Voted 4), as follows (underscore indicates new text, ~~striketrough~~ indicates deletions):

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the sole mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, ~~unapproved experimental drugs~~, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to ~~unapproved experimental medications~~ such drugs under the FDA Expanded Access Program; further,

To advocate that ~~the IND applicants for an investigational new drug or a new drug application~~ the IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the ~~experimental~~ drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol.

In response to a growing patient demand and profusion of state legislation, the Council discussed the dire situation faced by patients who have a terminal illness and have tried all available treatments or have been excluded from some. The Council felt that patients still need to have access to therapies under the purview of the FDA approval process. It acknowledged the need for appropriate access by the patient as well as appropriate review of the patient need within the context of the FDA expanded access program. The Council reviewed ASHP policies 0013, [Patient's Right to Choose](#), and 1411, [Expedited Pathways for Drug Approval](#). It concluded that there was a policy gap in addressing these state legislative proposals as well as advocating for improvement in FDA's Expanded Access program. The Council felt that FDA's

Expanded Access program is the preferred route for patient access.

## 9

### Approval of Biosimilar Medications

- 1 To encourage the development of safe and effective biosimilar medications in order to
- 2 make such medications more affordable and accessible; further,
- 3 To encourage research on the safety, effectiveness, and interchangeability of biosimilar
- 4 medications; further,
- 5 To support legislation and regulation to allow Food and Drug Administration (FDA)
- 6 approval of biosimilar medications; further,
- 7 To support legislation and regulation to allow FDA approval of biosimilar medications
- 8 that are also determined by the FDA to be interchangeable and therefore may be
- 9 substituted for the reference product without the intervention of the prescriber;
- 10 further,
- 11 To oppose the implementation of any state laws regarding biosimilar interchangeability
- 12 prior to finalization of FDA guidance; further,
- 13 To oppose any state legislation that would require a pharmacist to notify a prescriber
- 14 when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,
- 15 To require postmarketing surveillance for all biosimilar medications to ensure their
- 16 continued safety, effectiveness, purity, quality, identity, and strength; further,
- 17 To advocate for adequate reimbursement for biosimilar medications that are deemed
- 18 interchangeable; further,
- 19 To promote and develop ASHP-directed education of pharmacists about biosimilar
- 20 medications and their appropriate use within hospitals and health systems; further,
- 21 To advocate and encourage pharmacist evaluation and the application of the formulary
- 22 system before biosimilar medications are used in hospitals and health systems.

(Note: This policy would supersede ASHP policy 1409.)

**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; filgrastim-sndz should be ready for market by April 2015. Additional biosimilar applications are likely to be approved by the FDA this year.

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 2015, legislation in eight states (Delaware, Florida, Indiana, Massachusetts, North Dakota, Oregon, Utah, and Virginia) became law. In the 2015 state legislative session, there are fifteen states (Colorado, Georgia, Hawaii, Idaho, Illinois, Maryland, Mississippi, New Jersey, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Virginia and Washington) that have introduced legislation on biosimilars.

In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, a 2015 Georgia Senate bill would require 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. The Council felt that the FDA's determination of interchangeability is all that is needed in order to substitute the biosimilar with the reference product.

**Background**

The Council voted to recommend amending ASHP policy 1409, Approval of Biosimilar Medications, as follows (underscore indicates new text):

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

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

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

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be

substituted for the reference product without the intervention of the prescriber; further,

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

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

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

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

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

(Note: This policy would supersede ASHP policy 1409.)

The Council amended the policy to address proposed legislation that would require the pharmacist to notify the prescriber when an interchangeable biosimilar product is substituted.

The Council also discussed whether to strike the clause opposing the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance, since state legislation regarding interchangeability is already being proposed, but the Council concluded that until the FDA provides guidance about interchangeability, the clause is necessary.

## 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.)

- [Dispensing by Nonpharmacists and Nonprescribers](#) (0010)
- [FDA's Public Health Mission](#) (0012)
- [Patient's Right To Choose](#) (0013)
- [Postmarketing Safety Studies](#) (0515)
- [Mandatory Registry of Clinical Trials](#) (0516)

- [Health Insurance Coverage for U.S. Residents](#) (1001)
- [Risk Evaluation and Mitigation Strategies](#) (1002)
- [FDA Authority on Recalls](#) (1003)
- [Postmarketing Comparative Clinical and Pharmacoeconomic Studies](#) (1004)
- [Medication Therapy Management](#) (1005)
- [Definition of Meaningful Use of Health Information Technology](#) (1006)
- [Regulation of Home Medical Equipment Medication Products and Devices](#) (1007)
- [Employment Classification and Duty Hours of Pharmacy Residents](#) (1008)

## Other Council Activity

### State and Local Recognition of Pharmacists as Providers

In addition to its recommended policy relating to health policy development, the Council discussed additional actions that would inform members working in ambulatory care. As mentioned in the policy recommendation above, the Council agreed to develop a document that would define terms currently used in advocacy to recognize pharmacists as providers. As states begin to use terms such as *advanced practice pharmacist* and *pharmacist clinician*, the Council believed it was increasingly important to define these terms to provide consistency and understanding among policymakers. Specifically, the Council recommended that quality measures be developed to assist members as part of a toolkit to develop and enhance their practices. Other suggested actions included surveys of practice sites to understand best practices and innovations that can be adopted by members.

### Use of Compounded Drugs for Lethal Injection

The Council reviewed recent complications regarding state capital punishment executions via lethal injection. In keeping within its purview, the Council confined its discussion to the use of compounded drugs, the impact on shortages, and the need for more transparency concerning the supplier of compounded drugs. It noted the discussion by the Council on Pharmacy Practice concerning the role of any pharmacist participating in lethal injection.

The Council noted the need for more transparency concerning the supplier of lethal injection products to correctional facilities in the wake of recent incidents in which there were medication-related complications in carrying out the death sentence.

The Council also discussed the need to assist state affiliates as they encounter this issue, particularly as it impacts a potential shortage on widely used products.

### Medical Marijuana Regulation

The Council discussed the current conflict in some states that allow for the use of medical marijuana and the federal prohibition on its use since it is classified as a Schedule I controlled substance that lacks any legitimate medical use. It reviewed a summary of state laws regulating medical use of marijuana and a memorandum from the federal Department of Justice

concerning its enforcement of the Controlled Substances Act. The Council concluded that ASHP policy 1101, [Medical Marijuana](#), was still appropriate and recommended that other actions such as informing members about safeguarding their DEA registration would be useful.

Council members also discussed how to account for a patient's use of medical marijuana on their medical record as part of medication reconciliation. The Council noted that with the advent of the electronic medical record, health information exchanges would transmit this information across state lines and potentially be available to others in states that do not permit medical marijuana.

## Incentives for Drug Research and Development

The Council reviewed recent policy proposals and hearings by the House Committee on Energy and Commerce to stimulate development of drugs for unmet needs. It also reviewed existing ASHP policies concerning the drug approval process, including pre-and postmarketing studies. The Council did not develop any policy proposals at this time. Instead, the Council wanted to continue to study the issue since it was not likely that there would be congressional action until late 2015 or 2016 in conjunction with the reauthorization of user fee authority for the FDA.

The Council also discussed the proposed 21st Century Cures Act to help guide ASHP advocacy on the topic. The Council concluded that existing policy was adequate to address the legislation as currently proposed but that additional review and comments from ASHP section members may be valuable. Council members suggested that the proposed legislation be monitored as it evolves and reconsidered at future meetings.

## Product Labeling to Aid in Proper Waste Disposal

The Council reviewed a recommendation from the House of Delegates that sought ASHP advocacy to require inclusion of the waste disposal method (or waste stream) on the product labeling. The Council reviewed ASHP policy 0903, [Pharmaceutical Waste](#), and believed that it was sufficient to provide for advocacy on this issue.

## Medicare Part D Protected Drug Classes

The Council discussed recent proposals by the Centers for Medicare & Medicaid Services (CMS) to remove antipsychotics, antidepressants, and immunosuppressants as protected drug classes for Part D coverage. After receiving stakeholder input, CMS withdrew its proposal assuring patient access to these medications. However, the Council noted the need for ongoing education of the membership, particularly in the ambulatory environment since this proposal relates to Part D coverage. The Council also reviewed policy 0813, [Medicare Prescription Drug Benefit](#), and found that it was sufficient to use in advocacy on this issue.

## Differences Between Preferred and Any Willing Provider Pricing Under Medicare Part D

The Council discussed a recent study by CMS that showed some preferred pharmacies have higher negotiated prices than non-network pharmacies under the Part D drug program. The Council reviewed policy 0813 and found that it was sufficient to use in advocacy on this issue.



pharmacists advancing healthcare

# House of Delegates

## Board of Directors Report on the Council on Therapeutics (Final)

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

Paul Bush, *Board Liaison*

### Council Members

- Kersten Weber-Tatarelis, *Chair* (Illinois)
- Daniel Rackham, *Vice Chair* (Oregon)
- Abimbola Farinde (Texas)
- Ali McBride (Arizona)
- Pamela Phelps (Minnesota)
- Jennifer Reddan (Indiana)
- Christina Rivers (Illinois)
- Daryl Schiller (New Jersey)
- Casey White (Tennessee)
- Rena Gosser, *New Practitioner* (Wisconsin)
- Rachel Backert, *Student* (West Virginia)
- Shekhar Mehta, *Secretary*

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## Policy Recommendations

### 1

### Naloxone Availability

- 1 To recognize the potential public health benefits of broader use of naloxone for opioid reversal by properly trained individuals; further,
- 2
- 3 To support efforts to safely expand access to naloxone; further,
- 4
- 5 To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone only after counseling by a healthcare professional on proper administration, safe use, and appropriate follow-up care; further,
- 6
- 7 To foster education on the role of naloxone in opioid reversal.

#### **Rationale**

According to the Centers for Disease Control and Prevention (CDC), prescription drug abuse is a national epidemic. Deaths from prescription opioid overdose number 10,000 per year; in contrast, deaths from heroin overdose number 2000. People at risk for opioid overdose include not only substance abusers, but also opioid-naive patients, such as those being admitted for or discharged from ambulatory surgery.

Naloxone is a reversal agent that rapidly rescues patients from narcotic overdose by displacing mu2 opioid receptors in the brain. Naloxone has an excellent safety profile. The World Health Organization includes naloxone on its model list of essential medications.

Evidence shows a clear public health benefit from expanding access to naloxone. Although naloxone requires a prescription, a number of states have implemented programs to ensure liberal access to this lifesaving medication. As of 2014, there were 188 community-based programs operating in 26 states, and those programs had pronounced success in saving lives. In Massachusetts alone, almost 3000 overdoses were reversed.

Healthcare professional organizations have endorsed expanded access to naloxone, including the American Medical Association. The Veterans Affairs administration has implemented a naloxone program, with 28,000 opioid reversal kits made available. Issues of legal liability for persons administering naloxone are being addressed as well: over 20 states have amended their laws to protect lay administrators of naloxone from civil or criminal liability. There is also substantial congressional support to allow police officers and first responders to carry naloxone. The Opioid Overdose Reduction Act of 2014 (S. 2092) would provide immunity from civil suits for individuals trained to administer naloxone for opioid overdose reversal.

Expanded access would require appropriate education for those administering the drug, training on safe administration, and recommendations on follow-up care with abuse treatment programs for treated individuals. The FDA-approved formulation for opioid reversal is administered via subcutaneous injection, something caregivers or peers may have difficulty doing properly. Several pilot and model programs, such as the Staying Alive program developed by the Baltimore City Health Department, have successfully offered training for drug abusers to respond to opioid overdose, however. A nasal device is also available, and data collected from emergency response situations has shown that intranasal naloxone is as effective as transdermal routes in rapid opioid reversal. It costs approximately ten times that of standard formulations, and may carry the same safety profile and concerns, but would be easier for lay people to administer.

### **Background**

The Council considered the safety profile of naloxone, the public health impact of the opioid overdose epidemic, current trends in legislation and state programs, and availability of naloxone as a life-saving agent. Naloxone has a shorter half-life than the opioid analgesics it is intended to reverse, and there may be some potential concerns about post-administration respiratory depression. Another concern was increased diversion from drug use-treatment programs with increased availability. Members expressed concern that drug abusers may not seek comprehensive substance abuse treatment if they have access to a community-administered reversal agent. The Council determined there is currently no evidence that naloxone availability increases drug consumption. There is also no evidence that reversal contributes to a delay in entry into drug abuse treatment programs.

The Council also considered expanded access of naloxone in relation to previous discussions on intermediate drug categories and categorization as a nonprescription medication. Council members considered the safety profile and risk-benefit ratio of naloxone compared to available nonprescription medications. Council members questioned whether consumers would be able to interpret and understand nonprescription labeling for naloxone. Members noted that injectable naloxone is the only formulation that has the labeled indication for opioid reversal, and thus is the only formulation that could be transitioned to nonprescription status for that purpose. The Council acknowledged that appropriate use and access to naloxone requires training on safe administration and follow-up care. Some Council members mentioned the risk of seizures for those with heart disease. However, the pilot and model programs (such as the Staying Alive program developed by the Baltimore City Health Department) have had some success in training drug abusers to respond to opioid overdose. The Council also compared naloxone to other lifesaving reversal agents such as glucagon.

The Council examined existing ASHP policy on pain management and the [ASHP Statement on the Pharmacist's Role in Substance Abuse, Prevention, Education, and Assistance](#) and did not find policy that directly speaks to naloxone availability and opioid overdose.

## 2

## Complementary and Alternative Medicine in Patient Care

- 1 To promote awareness of the impacts of complementary and alternative (CAM)
- 2 products on patient care, particularly regarding drug interactions and medication
- 3 safety; further,
  
- 4 To advocate for the documentation of CAM products in the electronic health record to
- 5 improve patient safety; further,
  
- 6 To advocate for the inclusion of information about CAM products and their
- 7 characteristics in medication-related databases; further,
  
- 8 To provide education on the impacts of CAM products on patient care in healthcare
- 9 organizations; further,
  
- 10 To foster the development of up-to-date and readily available resources about CAM
- 11 products, with special consideration to drug interactions and medication safety.

### **Rationale**

Complementary and alternative medicine (CAM) may be broadly defined to include biologically based practices, such as dietary supplements, proteins, amino acids, and functional foods; energy therapies; manipulative body-based methods; and mind-body medicine. It is estimated that 38% of adults and 12% of children use some form of CAM. In 2007, \$15 billion was spent on CAM in the U.S., and the worldwide market for dietary supplements alone is estimated to be \$68 billion.

In the [ASHP Statement on Use of Dietary Supplements](#), ASHP expressed its concern that the widespread, indiscriminate use of dietary supplements presents substantial risks to public health and detailed the basis of those concerns. Some dietary supplements are inherently unsafe, to all people or special populations. Lax regulation of dietary supplement manufacturing presents the risk of contamination or adulteration with harmful substances, including prescription medications. Some dietary supplements interact with medications and may therefore compromise, complicate, or delay effective treatment. Some patients, particularly those who cannot afford expensive medication regimens, may substitute ineffective alternatives for well-proven medical therapies. Product content (both active ingredient and excipients) is not standardized, therapeutic goals are vague, and evidence of efficacy and safety is absent or ambiguous. Although the National Center for Complementary and Alternative Medicine (NCCAM) is taking steps to address the gaps in information regarding CAM products, pharmacists (like other healthcare providers) are frustrated in fulfilling their professional

responsibility to provide patients with sound advice by the lack of reliable information about the safety and efficacy of CAM products.

Healthcare organizations take varying approaches to addressing CAM use. Some actively counsel patients against CAM use, others take a more integrative approach and accept the practice, and some even have clinics for referrals. There is, however, a gap in information about CAM use in healthcare organizations. A recent survey of 109 children's hospitals revealed that 44% report having written policies on dietary supplements, with 46% requiring that interactions be documented in the medical record. Another survey of 302 pharmacy directors found that 38% had no policy on dietary supplements. ASHP has long encouraged healthcare organizations to develop an institutional policy regarding the use of dietary supplements that would allow pharmacists and other healthcare practitioners to exercise their professional judgment while balancing patient autonomy and institutional concerns. Such policies should include promoting healthcare practitioner awareness of the potential impacts of CAM use and should encourage documentation of CAM use in the EHR so that pharmacists and other healthcare practitioners have the knowledge and information they need to treat and advise patients.

### **Background**

Council members discussed various concerns with CAM use, including toxicity, uneven product quality, active ingredient variability, interactions between CAM products and drugs, and CAM product impacts on diseases. The Council noted the ongoing lack of oversight of CAM products by the FDA and the limitations the FDA and Federal Trade Commission face in regulating manufacture and promotion of dietary supplements because they are considered functional foods.

The Council noted that drug product costs, particularly among special populations such as oncology patients, can be significant. Prescription (and even nonprescription) medications can be much more costly than CAM alternatives. The Council expressed concern that patients might make a financial decision to shift away from evidence-based therapies in favor of alternative treatments.

The Council considered the variety of approaches healthcare organizations use to address CAM. Some institutions proactively refer patients to CAM clinics; others actively discourage use. The importance of comprehensive medication reconciliation, including CAM, was emphasized by the Council. The Council acknowledged that pharmacists have a responsibility to educate patients and inform them of the variability of CAM products. The Council agreed that guidance should focus on a positive approach, with consideration given to patient preference. The Council noted the desperate need for evidence-based information. An arm of the NIH, the National Center for Complementary and Alternative Medicine (NCCAM), is responsible for increasing the amount of research on CAM products, but the lack of standardization makes assessing comparative effectiveness challenging. The Council also noted that the United States Pharmacopoeia is the only organization certifying dietary supplement products.

ASHP members would benefit greatly from guidance and standards of practice when addressing CAM. The Council acknowledged the importance of the patient perspective on CAM and

suggested that pharmacists are the professionals to serve as facilitators in understanding existing information and treatment modalities. The Council agreed that a toolkit or resource of currently available existing information would be beneficial to members and practitioners.

## 3

### Development of Abuse-Resistant Narcotics

- 1 To advocate that the Food and Drug Administration investigate the efficacy of abuse-resistant formulations in preventing prescription drug abuse.
- 2

#### **Rationale**

The abuse potential of prescription narcotic medications has a large impact on public health. In October 2013, Zohydro, a long-acting formulation of hydrocodone without abuse-resistant features, was approved by the FDA against the recommendation of an FDA advisory committee. Some states and localities then initiated efforts to ban such agents. A coalition that includes 29 state attorneys general has formed to reverse the approval. In March 2014, the governor of Massachusetts attempted to ban the sale of Zohydro in the state, but a court ruled the ban unconstitutional. Six state attorneys general have drafted a letter to the Secretary of Health and Human Services questioning the FDA decision to approve Zohydro.

Despite the groundswell of support for abuse-resistant opioid formulations, there is not strong evidence that such formulations deter abuse. One study of 232,874 patients across 437 facilities found an increase in abuse prevalence of all opioids after introduction of an abuse-resistant formulation. That study showed little success in deterring abuse, finding instead that patients had switched to alternative drugs. There may also be unintended consequences of preferring abuse-resistant formulations to regular formulations, such as increased costs borne by patients who legitimately need the medications.

Addressing the growing rate of opioid abuse will require a multifaceted strategy; no one tactic will solve the problem. While ASHP supports measures such as abuse-resistant formulations and rescheduling to prevent abuse of opioids, more research is necessary to determine which tactics are the most effective at deterring abuse.

#### **Background**

The Council considered ASHP's position on new opioid products without abuse-resistant features. Council members reviewed the current landscape of opioid abuse and examined research on the impact of abuse-resistant features on opioid addiction. Council members shared personal observations of a decrease in oxycodone abuse once abuse-resistant features were introduced, but also noted a compensating increase in abuse of other narcotics. Members also recognized the increased costs associated with abuse-resistant formulations, specifically for cancer patients. Chronic pain patient preferences were also considered.

The Council also examined other methods of deterring abuse, such as rescheduling drugs with

high abuse potential. In 2012, the Council discussed the rescheduling of hydrocodone-containing products and recommended advocating for rescheduling based on the potential for abuse. The Drug Enforcement Administration has since moved hydrocodone-containing products to Schedule II. Members discussed methods of enforcing appropriate selection and prescribing of narcotics and noted that risk evaluation and mitigation strategies (REMS) are not sufficient to alleviate the problem of opioid abuse. The Council acknowledged that patients are able to obtain these medications through state Medicaid programs.

The Council reviewed [ASHP policy 0303, Pharmacy Drug Theft](#), which discusses methods to curb abuse, as well as the [ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance](#). Members felt that these documents should include information relevant to abuse and diversion.

## 4

### Quality Patient Medication Information

- 1 To support efforts by the Food and Drug Administration (FDA) and other stakeholders
- 2 to improve the quality, consistency, and simplicity of written patient medication
- 3 information (PMI); further,
  
- 4 To encourage the FDA to work in collaboration with patient advocates and other
- 5 stakeholders to create evidence-based models and standards, including establishment
- 6 of a universal literacy level, for PMI; further,
  
- 7 To advocate that research be conducted to validate these models in actual-use studies
- 8 in pertinent patient populations; further,
  
- 9 To advocate that FDA explore alternative models of PMI content development and
- 10 maintenance that will ensure the highest level of accuracy, consistency, and currency;
- 11 further,
  
- 12 To advocate that the FDA engage a single third-party author to provide editorial control
- 13 of a highly structured, publicly accessible central repository of PMI in a format that is
- 14 suitable for ready export; further,
  
- 15 To advocate for laws and regulations that would require all dispensers of medications
- 16 to comply with FDA-established standards for unalterable content, format, and
- 17 distribution of PMI.

(Note: This policy would supersede ASHP policy 1012.)

#### **Rationale**

ASHP supports the intent of efforts to improve the quality, consistency, and simplicity of patient medication information (PMI), which the FDA defines as a single standard document for

communicating essential information about prescription drugs. However, because these efforts were largely based on consensus of expert opinion, rather than quantitative and well-documented evidence, and because subsequent studies were conducted using expert-based focus groups and other study designs that do not reflect typical patients and under flawed methodology, ASHP encourages the development of evidence-based models for PMI that are designed to support desired outcomes (e.g., better medication use, improved patient safety). In addition, research to validate the effectiveness of any new PMI models under real-use conditions by actual patients, including establishment of a universal literacy level for PMI, should be encouraged. Evidence to establish the essential PMI content needed for the safe and effective use of medications by patients remains to be determined.

Although drug information publishers have made significant progress in improving the quality of PMI, this content is often truncated or provided in illegible formats to accommodate size restrictions or marketing information on patient drug information leaflets that are stapled to prescription packaging.

Because of the FDA's long history of failure to ensure the consistency, currency, and accuracy of the professional labeling on which PMI would be based; potential for inclusion of biased or promotional information; and the resulting patient confusion and possible harm, ASHP strongly opposes FDA's current proposal for manufacturer-authored PMI that would not be subject to FDA review. Approximately 85% of professional labeling has not been reviewed or updated since 1992 to reflect FDA's current standard for the Physician Labeling Rule (PLR) format. In addition, numerous inconsistencies and inaccuracies in such labeling continue. Given these limitations, the majority of information on which PMI would be based under FDA's proposal would not be likely to "enhance the safe and effective use of prescription drug products and in turn reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information," which is the [main goal of the FDA requirements](#).

ASHP further advocates that state legislatures and regulatory agencies require that all dispensers distribute PMI according to FDA-established standards and be held accountable if PMI content or format is modified in a manner that results in nonconformance to the standards.

Creation and maintenance of PMI by a single third-party author (subject to FDA-contracted standards and quality assurance metrics) would provide clear, concise, unbiased, evidence-based PMI that is both timely and consistent for the same drug and for relevant information within the same drug class. Such coordination of the medication information database would allow for consistency in style and content, as well as more frequently updated content

### **Background**

The Council voted to revise ASHP policy 1012 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to

improve the quality, consistency, and simplicity of written ~~consumer~~ patient medication information (~~CMI~~ PMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level, for PMI ~~CMI~~; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of PMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly accessible central repository of PMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would ~~state boards of pharmacy~~ require ~~pharmacies~~ all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of PMI.

The Council recognized that the FDA and other stakeholders are continuing to evaluate best practices to improve the quality, consistency, and simplicity of written PMI and recommended that this policy not be retired but rather updated to reflect current issues. The Council noted that under FDA's current proposal, PMI would be based solely on each manufacturer's own professional labeling, which has well-documented limitations.

Council members gratefully acknowledged information provided by ASHP staff members Barbara Young and Gerry McEvoy on recent activity of FDA in addressing standardization of patient medication information. Many stakeholders believe in one source of documentation, although the optimum length of such documentation remains unclear. There are unfortunately no studies or evidence evaluating patient comprehension of information or content.

## 5

## Safety and Effectiveness of Ethanol Treatment for Alcohol Withdrawal Syndrome

- 1 To oppose the use of oral or intravenous ethanol for the prevention or treatment of
- 2 alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety
- 3 profile; further,
- 4 To support hospital and health-system efforts that prohibit the use of oral or
- 5 intravenous ethanol therapies to treat AWS; further,
- 6 To educate clinicians about the availability of alternative therapies for AWS.

(Note: This policy would supersede ASHP policy 1010.)

### **Rationale**

Alcohol withdrawal syndrome (AWS), which can delay patient recovery and interfere with response to therapy, is often prevented or treated using oral or intravenous ethanol. Based on a review of the available evidence, including treatment guidelines from the American Society of Addiction Medicine (ASAM), ASHP opposes the use of these therapies to prevent or treat AWS. Limited and conflicting evidence of effectiveness, inability to achieve accurate and consistent dosing and blood levels, and the availability of more effective and safer therapies are among the reasons to oppose use of ethanol to prevent or treat AWS symptoms. One evidence-based therapy for treatment of AWS is pharmacotherapy with benzodiazepines. Guidelines from the American Association of Family Physicians recommend benzodiazepines on a fixed schedule for AWS, outpatient detoxification, and enrollment in an alcohol treatment program. For these reasons, ASHP supports efforts to prohibit use of these therapies for AWS and advocates education to a variety of healthcare practitioner audiences to increase awareness of appropriate alternative therapies. ASHP continues to support the use of ethanol for the treatment of acute alcohol poisoning, which is described in evidence-based guidelines.

### **Background**

The Council recommended revising policy 1010 as follows (~~strike through~~ indicates deletion):

To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that ~~restrict or~~ prohibit the use of oral or intravenous ethanol therapies to treat AWS; further,

To educate clinicians about the availability of alternative therapies for AWS.

The Council has assessed the risk-benefit ratio of using ethanol to treat AWS compared to

existing recommended therapies and found consensus that existing recommended therapies are safer and more effective. There is no current evidence that supports the use of oral or IV ethanol for AWS. There are significant ethical concerns over the use of ethanol in the management of withdrawal. The Council argued against condoning the use of IV ethanol. Council members encouraged striving for best practices and recommended striking the second statement of the policy that suggests restriction, rather than prohibition, is acceptable. The Council believes this statement contradicts the first statement of the policy opposing the use of oral and IV ethanol in prevention and treatment of AWS.

## 6

### Research on Drug Use in Obese Patients

- 1 To encourage drug product manufacturers to conduct pharmacokinetic and
- 2 pharmacodynamic research in obese patients to facilitate safe and effective dosing of
- 3 medications in this patient population, especially for medications most likely to be
- 4 affected by obesity; further,
  
- 5 To encourage manufacturers to include in the Food and Drug Administration (FDA) –
- 6 approved labeling detailed information on characteristics of individuals enrolled in drug
- 7 dosing studies; further,
  
- 8 To advocate that the FDA develop guidance for the design and reporting of studies that
- 9 support dosing recommendations in obese patients; further,
  
- 10 To advocate for increased enrollment and outcomes reporting of obese patients in
- 11 clinical trials of medications; further,
  
- 12 To encourage independent research on the clinical significance of obesity on drug use,
- 13 as well as the reporting and dissemination of this information via published literature,
- 14 patient registries, and other mechanisms.

(Note: This policy would supersede ASHP policy 1013.)

#### **Rationale**

Given the growing rate of obesity in the United States, ASHP is concerned about the uncertainty surrounding how obesity affects drug dosing, effectiveness, and safety. The FDA does not require that studies of obese patient populations be performed, despite the growing proportion of obese patients in America. Obese patients are subject to variable pharmacokinetic effects of oral and injectable therapeutic agents. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies of obese patients, especially for drugs for which obesity is expected to have significant clinical impact (e.g., antimicrobials, highly lipophilic drugs, etc.). If these voluntary studies are not completed, then manufacturers should include in the FDA-approved labeling complete information on the population enrolled

in dosing studies and the methods used to determine dosing so that clinicians can assess the extent to which that population reflects patients being treated.

ASHP advocates that the FDA develop guidance for voluntary drug dosing studies of obese patients that would define study design and reporting with the intent of standardizing this research to the extent possible. The need for this guidance is supported by the complexity of drug dosing for obese patients, which varies based on drug and patient characteristics. A paucity of research in this patient population is noted, which is similar to the lack of preapproval studies in geriatric and pediatric patients. Such studies could help standardize research methods and promote comparative effectiveness research. ASHP also encourages independent clinical and practice-based research to further define clinical use of drugs in the treatment of obese patients, as well as clinician reporting of patient experience via published articles and clinical registries.

### **Background**

The Council recommended amending ASHP policy 1013 as follows (underscore indicates new text; ~~strike through~~ indicates deletions):

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in obese patients to facilitate safe and effective dosing of medications in this patient population, especially for medications most likely to be affected by obesity; further,

To encourage manufacturers to include in the Food and Drug Administration (FDA) – approved labeling detailed information on characteristics of individuals enrolled in drug dosing studies; further,

To advocate that the FDA develop guidance for the design and reporting of studies that support dosing recommendations in obese patients; further,

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

To encourage independent research on the clinical significance of obesity on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms.

The Council questioned whether postmarketing studies and data can provide information on pharmacokinetic issues such as distribution and absorption of agents in obese patients. For many agents the historical trend has been to proceed conservatively and base dosing on ideal body weight. For some agents the volume of distribution has varying effects and drug concentrations can increase over time. The Council recognized that many oncology agents are capped at a particular dose. The Council found that there was insufficient evidence and research on how obesity affects drug distribution and efficacy of medications.

The Council ultimately believed that because of the growing prevalence of obesity in the U.S., it will be increasingly important to understand how obesity affects the safety and effectiveness of therapeutic agents. Antimicrobial agents and lipophilic drugs have varying characteristics when administered in this special population. The Council felt subgroup analysis of special populations should be required during Phase I and II clinical studies.

## 7

## Chemotherapy Parity

- 1 To advocate that all prescription insurance payers design plans so that patient cost
- 2 sharing for oral chemotherapy is no higher than that for intravenous chemotherapy;
- 3 further,
- 4 To continue to foster the development of best practices, including adherence
- 5 monitoring strategies, and education on the safe use and management of oral
- 6 chemotherapy agents.

### **Rationale**

Chemotherapy is traditionally thought of as an intravenous agent, but the availability of oral chemotherapy agents has been steadily increasing. The FDA has approved 17 oral chemotherapy agents over the past 10 years. Thirty percent of the 900 current chemotherapy agents in development are oral agents. These agents play a significant role in treatment modalities and are sometimes the only agent of choice (e.g., oral imatinib mesylate for chronic myelogenous leukemia).

Unfortunately, cost sharing for these novel agents is not consistent across different types of medical coverage and prescription drug plans. Pharmaceutical manufacturers recoup research and development costs by charging more for novel agents, whose costs can soar as high as \$8,000 to \$12,000 per month. Well-established intravenous agents are less expensive and are often covered under systems such as Medicare Part B. Changing treatment from intravenous to oral agents can shift their billing to prescription drug benefits. Private health insurance typically contains varying tiers of copayment, with chemotherapy belonging to upper tiers. According to the Hematology/Oncology Pharmacists Association (HOPA), 25–33% of the cost of these agents is shared with patients. Cancer patients are over two-and-a-half times more likely to file for bankruptcy than patients with other conditions.

Given the expense, cost-sharing can have a significant impact on patient access and adherence. A recent Health Affairs survey found that over 50% of practitioners agree that costs influence treatment decisions, but only 46% of practitioners discuss costs with patients. Although patient assistance programs can help some patient with the cost burden, the requirements associated with such programs can be complex, and the programs typically do not cover gaps left by federally funded programs such as Medicare.

Since 2008, over 26 states have passed oral chemotherapy parity laws to ensure equal insurance coverage of oral and intravenous chemotherapy agents and preserve patient access to these therapies. Federal chemotherapy parity legislation (H.R. 1801) has also been introduced. Ensuring parity between oral and intravenous chemotherapy reimbursement will expand patient access to needed medications and improve outcomes of care.

Pharmacists have a responsibility to assure safe, effective, and appropriate use of self-administered oral chemotherapy agents. Dispensing and administration of intravenous chemotherapy treatments has been reserved for clinics, where robust quality and monitoring processes address safety concerns. New oral chemotherapy agents can be self-administered in a variety of settings, where the safety checkpoints that are standard in infusion clinics are absent. All healthcare professionals involved in the collaborative care of cancer patients will require training to use these high-risk and costly oral chemotherapy agents safely and wisely. Pharmacists have been and will continue to be key leaders in addressing safety issues and evaluating the comparative effectiveness of chemotherapy across settings.

### **Background**

The Council voted to recommend amending its September policy recommendation, Chemotherapy Parity (Voted 4), as follows (underscore indicates new text, ~~strikethrough~~ indicates deletions):

To advocate that all prescription insurance payers ~~provide equal access to and coverage for oral and intravenous chemotherapy agents~~ design plans so that patient cost sharing for oral chemotherapy that is no higher than that for intravenous chemotherapy; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of oral chemotherapy agents.

The Council reflected on the Board and ASHP Connect discussion of its Policy Week recommendation when reconsidering this proposed policy. A notable concern about the proposed policy's original language identified by the Council was the use of the term "insurance coverage," which could be perceived as a mandate to payers, rather than equitable cost sharing practices, which the Council had intended to address. The Council noted that in calculating costs associated with therapy, payers may include administrative costs associated with outpatient oncology clinics.

Council members confirmed their intent to separate the issues of cost sharing and the development of best practices in the safe use and management of oral chemotherapy. Members emphasized the importance of medication safety in this novel use of hazardous agents and recommended retaining a statement on continuing development of best practices in the proposed policy. The Council reaffirmed the determination during Policy Week discussions to work with The Council on Pharmacy Practice to consider safety of oral chemotherapy safety practices in revisions to the guidelines on preventing medication errors with chemotherapy and biotherapy.

The Board also asked whether the policy should address comparative effectiveness of chemotherapy treatments as well as medication safety. Current clinical evidence on comparative effectiveness of chemotherapy treatments is sparse, and the Council acknowledged challenges with conducting such studies. The Council's main concern in drafting the policy was with the differences in levels of coverage for oral and intravenous chemotherapy parity rather than varying degrees of outcomes. The Council was hesitant to develop policy on quality of life and survival as patient outcomes, given a lack of substantiating literature on the comparative effectiveness of the treatments.

## 8

## Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship

- 1 To strongly advocate involvement of pharmacists in the clarification of penicillin
- 2 allergy, intolerance, and adverse drug events; further,
- 3 To advocate for documentation of penicillin allergy in the medical record to facilitate
- 4 appropriate antimicrobial selection; further,
- 5 To recommend the use of penicillin skin testing in appropriate candidates when
- 6 clinically indicated to reduce the incidence of inappropriate antimicrobial selection.

### **Rationale**

The appropriate use of antibiotics and antibiotic stewardship is an urgent public health concern. Policymakers have emphasized the judicious use of antibiotics through proposed legislation such as the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) and Antibiotic Development to Advance Patient Treatment (ADAPT) acts, which has been incorporated into drafts of the 21st Century Cures legislation.

Evidence linking the inappropriate use of antibiotics and emergence of drug resistance organisms has been accumulating since the 1980s. According to a 2013 Centers for Disease Control and Prevention (CDC) report, 2 million people are infected with resistant bacteria each year in the U.S. and 23,000 die each year. *Clostridium difficile* infections alone cause 250,000 hospitalizations each year. It is estimated that 31–51% of vancomycin prescriptions are due to penicillin allergy. Cross-sensitivity between cephalosporins and penicillin is 8%, with anaphylactic reactions occurring in 0.4% of patients. Ninety percent of patients with a negative penicillin allergy skin test can be switched to penicillin, with additional minor determinants adding another 30% of missed patients. At some institutions, 20% report penicillin allergy, while only 0.9% actually have the allergy.

The American Academy of Allergy and Immunology, as part of a Choosing Wisely campaign, recommends against the overuse of non-beta lactam antibiotics in patients with a history of penicillin allergy, without appropriate evaluation. In a research abstract from the Canadian Society of Allergy and Clinical Immunology meeting in 2014, researchers found that only 15% of

hospital-discharged patients notified a family physician of a negative penicillin allergy evaluation, and at the same time, 30% were still listed as penicillin allergic upon readmission to the hospital.

### **Background**

In September's Council meeting, the Council proposed that ASHP create commentary on this issue in AJHP or similar spaces. The Council reconsidered that recommendation in light of Board concerns that policy language would be more useful, as well as the fact that there is momentum throughout the government and healthcare community to strengthen antibiotic stewardship efforts. The Council reviewed proposed policy language created by Council members and staff in preparation for this meeting and approved the draft language as worded. There was some question about whether the phrase "electronic medical record" should be changed to simply "medical record" to encompass all medical records rather than just the subset of electronic records. There was also discussion of whether the policy should address cross-reactivity issues. Members agreed that cross-reactivity was a more specific operational issue and would be more appropriate in supplemental materials or operational guidance.

Council members acknowledged the urgency and importance of antibiotic stewardship efforts related to penicillin allergy skin testing. They also reviewed the evidence discussed during Policy Week meetings in September 2014, particularly research by Eric Macy on penicillin allergy skin testing, adverse reactions, and therapeutic use of antibiotics. The Council maintains the views and outcomes of the Policy Week discussions, including the need to increase awareness of the valuable role of penicillin-allergy skin testing as an antimicrobial stewardship practice and promoting the role of the pharmacist in identifying and stratifying true penicillin-allergic patients in health systems. The Council also recommended working collaboratively with other relevant organizations to incorporate penicillin-like agent allergy clarification into existing antimicrobial stewardship standards.

The Council was made aware of quality improvement initiatives being implemented through the Affordable Care Act, such as the incorporation of antimicrobial stewardship programs in health systems. ASHP continues to have strong relationships with partner organizations such as the Infectious Diseases Society of America (IDSA), and the Council felt it important to continue to collaborate with such organizations on public health issues.

The Council noted that the challenge of initiating skin testing, documenting results, and making lasting changes to a patient's allergy history may involve working collaboratively with other health professions and electronic health records vendors. The Council noted significant potential with collaborating organizations such as IDSA on skin testing educational efforts. Members noted that the Journal of Allergy and Immunology has recently published many articles on the effects of skin testing in health systems. The Council assessed the opportunity to collaborate with other organizations on creating education and practice standards on methodology and implementation of skin testing.

Council members noted that the [ASHP Statement on Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control](#) and IDSA guidelines on antimicrobial

stewardship do not address the importance of correctly identifying allergic patients and using strategies such as penicillin-allergy skin testing when indicated, and concluded that this absence presents a gap in general antibiotic stewardship effort across health systems

Council members discussed proposed official policy language on the topic, and the requirement that hospitals balance benefits and risks of skin testing along with the challenges of changes in documentation of allergy history.

## 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.)

- [Preservation of Antimicrobials for Medical Treatment](#) (1009)
- [Use of Surrogate Endpoints for FDA Approval of Drug Uses](#) (1011)

## Other Council Activity

### ASHP Statement on Over-the-Counter Availability of Statins

The Council voted to revise the ASHP Statement on Over-the-Counter Availability of Statins. The American College of Cardiology and the American Heart Association recently updated recommendations on the treatment of blood cholesterol to reduce cardiovascular risk. These recommendations have contributed updated information on the relevance of statin therapy for prevention of cardiovascular events. These recommendations and updated information should be considered and incorporated into a revision of the statement on over-the-counter (OTC) availability of statins. The revision process should also take into account existing ASHP documents on a proposed intermediate category of drugs.

The Council also recognized that there is an existing document on intermediate drug category class that mentions statins specifically. The Council proposes a change from the term “OTC” to “nonprescription” in order to be more aligned with existing policy and statements on intermediate drug categories.

### ASHP Statement on Criteria for an Intermediate Category of Drug Products

The Council voted to revise the ASHP Statement on Criteria for an Intermediate Category of Drug Products, with special consideration on striking the list of specific drugs in favor of more general statements.

The Council considered extensive previous Council discussions on this topic, most recently during a 2012 discussion on OTC availability of oral contraceptives. Members also considered discussion during the 2014 House of Delegates meeting on the ASHP policy on access to oral contraceptives. Comments provided to the FDA during a 2012 hearing supported the creation of such an intermediate category of drug products. ASHP supported the establishment of a paradigm subject to conditions that include availability from a pharmacist after appropriate patient assessment and consultation. ASHP advocated that the FDA make decisions on a case-by-case basis due to variable drug safety profiles and risk-benefit ratios of agents.

## ASHP Statement on Appropriate Off-Label Use of Medications

The Council voted to continue development of the ASHP Statement on Appropriate Off-Label Use of Medications, with consideration of special populations, electronic health records, workflow, and stated indications for off-label use.

The Council reviewed a draft of the ASHP Statement on Appropriate Off-Label Use of Medications that updates the previous ASHP Statement on the Use of Unlabeled Medications from 1992. This statement was distributed for public member comment and the comments have been adjudicated.

## ASHP Policies Related to Abuse and Diversion of Controlled Substances

As a result of its discussion of abuse-resistant narcotics, the Council recommended that the Council on Pharmacy Management consider abuse and diversion of controlled substances in its review of policy 0303, Pharmacy Drug Theft, and that the Council on Pharmacy Practice consider abuse and diversion in its review of the [ASHP Statement on the Pharmacist's Role in Substance Abuse, Prevention, Education, and Assistance](#).

## Continued Involvement with Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines

ASHP has a significant history of endorsing guidelines that are relevant to our members' practice and adhere to guideline development recommendations from the Institute of Medicine. CPIC's [guideline development process](#) closely follows Institute of Medicine recommendations. The Consortium's guidelines address barriers to implementation of pharmacogenetic testing in clinical practice. Rather than suggesting when or whether a specific test should be ordered, the guidelines focus on how to interpret each test. CPIC assumes that genotyping will become widespread. In its discussion, the Council considered the example of existing genotyping for anticoagulants such as warfarin, and agreed on the importance of such information in clinical practice. The Council acknowledged that CPIC's approach is of value not only to ASHP membership but to healthcare practitioners as a whole. Previous CPIC recommendations endorsed by ASHP include:

- Guidelines for Cytochrome P450-2C19 genotype and clopidogrel therapy (September 2011)

- Guidelines for Codeine Therapy in the Context of Cytochrome P450 2D6 (CYP2D6) Genotype (September 2012)
- Guidelines for Thiopurine Methyltransferase Genotype and Thiopurine Dosing (September 2013)

Because of CPIC's systematic approach to these recommendations, the Council felt it relevant to consider upcoming guidelines being developed by CPIC for endorsement by ASHP. These guidelines will have a significant impact on practice and will assist members in clinical decision making at the point of care. The Council believes close and continued work with the organization is warranted.

## Ambulatory Care Summit Recommendations

The council considered recent recommendations on ambulatory care released by ASHP and the ASHP Foundation. These forward-thinking recommendations speak to practice issues relevant to ambulatory care and associated services. The Council acknowledged these recommendations and noted the impact pharmacists can have on quality of care in outpatient and ambulatory care settings. The Council noted that the Ambulatory Care Summit Recommendations particularly related to the work of the Council on Therapeutics include the following:

2.8 - Pharmacists who provide ambulatory care services must partner with patients, families, and caregivers to set goals of therapy and promote accountability for self-management

4.5 - Pharmacists who provide ambulatory care services should apply quality improvement principles; research methods to assess the quality of their services, and disseminate the findings of such assessments

4.7 - Pharmacists who provide ambulatory care services should participate in research that supports their value in contributing to improved health outcomes.



pharmacists advancing healthcare

# House of Delegates

## Board of Directors Report on the Council on Education and Workforce Development (Final)

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

Ranee M. Runnebaum, *Board Liaison*

### Council Members

- Jay Rho, *Chair* (California)
- Kim Jones, *Vice Chair* (Tennessee)
- Philip Brummond (Wisconsin)
- Natalie Eddington (Maryland)
- Michelle Fraley (Kentucky)
- Mort Goldman (Ohio)
- Nancy Goodbar (South Carolina)
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- Meghan Swarthout (Maryland)
- Whitney White (Alabama)
- Grayson Peek, *New Practitioner* (North Carolina)
- Cassie Stewart, *Student* (West Virginia)
- JoAnn Harris, *Secretary*

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*(Click on title to view section)*

## Policy Recommendations

### 1

### Developing Leadership Competencies

- 1 To work with healthcare organization leadership to foster opportunities for pharmacy
- 2 practitioners to move into leadership roles; further,
  
- 3 To encourage leaders to seek out and mentor pharmacy practitioners in developing
- 4 administrative, managerial, and leadership skills; further,
  
- 5 To encourage pharmacy practitioners to obtain the skills necessary to pursue
- 6 administrative, managerial, and leadership roles; further,
  
- 7 To encourage colleges of pharmacy and ASHP state affiliates to collaborate in fostering
- 8 student leadership skills through development of co-curricular leadership
- 9 opportunities, leadership conferences, and other leadership promotion programs;
- 10 further,
  
- 11 To reaffirm that residency programs should develop leadership skills through
- 12 mentoring, training, and leadership opportunities; further,
  
- 13 To foster leadership skills for pharmacists to use on a daily basis in their roles as leaders
- 14 in patient care.

(Note: This policy would supersede ASHP policy 0509.)

#### **Rationale**

In their 2013 report, White and Enright anticipated a high rate of turnover of pharmacy directors and middle managers over the course of the coming decade. Healthcare organizations must address this ongoing challenge if there are to be a sufficient number of new directors and managers to fill those positions. Some of the factors that may contribute to a shortage of potential new leaders and managers include:

- New graduates frequently accept clinical positions or positions in drug distribution. After a few years, they may have a desire to assume managerial positions in health-system pharmacies, but training programs may not be convenient for them, and they may not have the resources to obtain training.
- Many health-system pharmacy management positions turn over infrequently. Prospective managers view those positions as unavailable for the near future. Therefore, there is little incentive to obtain training to be ready to move into those positions.

- Job satisfaction among pharmacy managers appears low to prospective managers.
- Frequent turnover in organizational administrative positions (above pharmacy) is frustrating to pharmacy directors, because they continually need to inform new administrators about the organization's medication-use strengths and weaknesses and the pharmacy department's roles, strategic plans, and priorities for sustaining quality and making improvements. In those turnover circumstances, diligently achieved pharmacy service improvements can sometimes be eroded and reversed. The ensuing frustration can induce pharmacy directors to depart voluntarily from management positions and make those positions unattractive to others.
- Flattening of organizational structures in healthcare organizations has eliminated numerous managerial positions in pharmacies, leaving fewer pharmacists to serve as mentors for prospective managers. Without good role models, it is difficult for pharmacists to gain good management experiences.
- Pharmacy management positions that combine clinical and management responsibilities sometimes allow little time for clinical work.
- Many pharmacists, even those in managerial positions, have no training in personnel administration. Skills such as conflict resolution and negotiation are rarely taught in pharmacy curricula but are very important in leadership positions.
- In some healthcare organizations, managers receive raises predicated on overall organizational or departmental performance. The compensation of some staff, however, may be based on individual performance. The differing bases can lead to instances in which the compensation of those supervised is higher than that of their managers. When that occurs, it can be a disincentive to individuals considering management positions.

Leadership and managerial potential in today's pharmacy students and new graduates is as high as it has ever been, but more effort is needed to nurture that potential and develop leadership and management skills in practice. Colleges of pharmacy, state associations, residency programs, and practitioners themselves need to foster the development of leadership and management skills. ASHP can help foster leadership competencies at all levels of practice through actions such as providing education about leadership and management roles, developing Web-based resources, and facilitating networking among leaders, managers, and those aspiring to those roles.

Leadership continues to be a critical area for development, as leadership is a necessary competency in the provision of patient care. There are multiple avenues available to pharmacists for leadership development and ASHP should take the lead in fostering awareness.

### **Background**

As part of sunset review, the Council voted to recommend amending ASHP policy 0509, Developing Leadership and Management Competencies, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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

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

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

To encourage colleges of pharmacy and ASHP state affiliates to ~~foster~~ collaborate in fostering student leadership skills ~~in students~~ through development ~~and enhancement~~ of ~~curricula~~ co-curricular leadership opportunities, leadership conferences, and other leadership promotion programs; further,

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

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

To encourage reaffirm that residency programs ~~to~~ should develop leadership skills ~~by~~ through mentoring, training, and ~~providing~~ leadership opportunities; further,

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

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

The Council believed that portions of policy 0509 are still appropriate, but other portions are no longer needed because subsequent developments have completed them or made the language redundant of other policies. For example, relevant residency standards now exist, including postgraduate year two (PGY2) residencies in health-system pharmacy administration. More colleges of pharmacy now offer combined degrees with a managerial emphasis. They also now offer co-curricular pharmacy practice experiences, some of which could be in leadership development experiences. Finally, the ASHP Research and Education Foundation established a Pharmacy Leadership Academy in 2006.

## 2

## Pharmacy Technician Training and Certification

- 1 To advocate that pharmacy technicians be required to have completed a pharmacy technician training program accredited by the Pharmacy Technician Accreditation Commission (PTAC) and to obtain and maintain Pharmacy Technician Certification Board certification; further,
- 2
- 3
- 4
- 5 To foster expansion of PTAC-accredited pharmacy technician training programs.

(Note: This policy would supersede ASHP policies 1015 and 0702.)

### **Rationale**

The recent partnership between ASHP and the Accreditation Council for Pharmacy Education (ACPE) to accredit pharmacy technician training programs could be an important inflection point leading to professionwide support for uniform education, training, and credentialing of pharmacy technicians. Such broad support may stimulate more uniform state statutes and regulations about pharmacy technicians. The requirement that pharmacy technicians should be graduates of PTAC-accredited training programs and should be certified by the Pharmacy Technician Certification Board (PTCB) mirrors the profession's approach to the education (first) and (then) licensure of pharmacists. Consistent with this model, PTCB will, in 2020, require that an individual sitting for the pharmacy technician certification examination be a graduate of a PTAC-accredited training program. Although programs currently accredited by ASHP will be granted accreditation by PTAC, the anticipated increase in demand for enrollment in PTAC-accredited training programs will require an expansion of the number and distribution of such programs.

### **Background**

As part of sunset review, the Council voted to recommend amending ASHP policy 1015, Minimum Hiring Standards for Pharmacy Technicians, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To ~~encourage employers to hire~~ advocate that pharmacy technicians ~~who have successfully~~ be required to have completed an ~~ASHP-accredited~~ pharmacy technician training program accredited by the Pharmacy Technician Accreditation Commission (PTAC) and are certified by the to obtain and maintain Pharmacy Technician Certification Board (~~PTCB~~) certification; further,

To ~~support employment practices that would permit hiring of pharmacy technician trainees only if those individuals (1) are required to both successfully complete an ASHP-~~

~~accredited pharmacy technician training program and successfully complete PTCB certification within 24 months of employment, and (2) are limited to positions with lesser responsibilities until they successfully complete such training and certification; further,~~

~~To encourage employers to require ongoing PTCB certification as a condition of continued employment; further,~~

To encourage foster expansion of ASHPPTAC-accredited pharmacy technician training programs.

Approval of this revision also would discontinue policy 0702, which reads:

To support the goal that pharmacy technicians entering the pharmacy workforce have completed an ASHP-accredited program of training; further,

To encourage expansion of ASHP-accredited pharmacy technician training programs.

The Council believes ASHP should adopt an unequivocal policy that pharmacy technicians should be graduates of ASHP-ACPE-accredited training programs and should be certified by the PTCB. The Council considered whether it seems self-serving to say in the policy that the accreditation must be “PTAC-accredited” and concluded that the accreditation is known to be sound. The Council hopes that these criteria will eventually be specifically stipulated in state statutes and regulations (similar to state requirements stipulating that pharmacist licensees must be graduates of ACPE-accredited colleges of pharmacy). The Council is also concerned that, until states act to be specific about this, unsound training programs will continue to flourish and there is potential for unsound alternative accreditation processes to evolve. Both are inconsistent with public need and safety.

The Council acknowledges that employers will have to work through how they handle the employment of current pharmacy technicians who do not meet these criteria. The Council believes employers should be allowed to decide that for themselves and that ASHP’s policy should not be prescriptive about the matter. In that respect, the Council suggested that the Council on Public Policy reexamine the specificity in policy 1216 with an aim toward possible revision.

ASHP could work with ACPE and the National Association of Boards of Pharmacy (NABP) to develop model language for state statutes and regulations. The states have the prerogative to decide for themselves whether (or how) to address currently employed pharmacy technicians that do not meet the criteria. The Council discussed but did not come to a conclusion about how graduates with a two-year degree from an Associate of Applied Science in Pharmacy Technology program will be handled with respect to the requirement for graduation from a PTAC-accredited program. Specific rules might be established in individual state regulations, and such programs might seek PTAC accreditation.

PTAC will assess programs that apply for accreditation, and a new accreditation standard has been created that will become effective in January 2015. At this time, the training requirements and accreditation will focus on core competencies that pharmacy technicians must have for work in any pharmacy setting, including hospitals, health systems, and retail pharmacies. No specific plans are underway at this time for accrediting training for differentiated sites, advanced roles, or advanced programs. ASHP and ACPE staff will be meeting soon with numerous stakeholders, including colleges of pharmacy, state boards of pharmacy, state pharmacy associations, and major pharmacy retail chain corporations to discuss the developments and opportunities for accredited training. Conversation with key unions that have pharmacy technicians as members may be useful as well. Some of the major pharmacy chain corporations already have programs accredited by ASHP. It is anticipated that more online tools for training will evolve. It will continue to be the case that certified graduates of accredited training programs may need additional local training for specific tasks.

The Council believed that the accreditation and certification changes ultimately will help foster a transformation of pharmacy technician from an occupation to a recognized career. The Council believed that a better-trained pharmacy technician workforce will enable work reforms in a wide variety of practice settings. It also is inevitable that more highly trained workers will be paid more than they are now, if for no other reason than to retain them in the face of recruitment by unrelated types of employers.

## 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.)

- [Residency Training for Pharmacists who Provide Direct Patient Care](#) (0005)
- [Communication Among Health-System Pharmacy Practitioners, Patients, and Other Health Care Providers](#) (0510)
- [Interprofessional Education and Training](#) (1014)

## Other Council Activity

### Medication-Use Safety Education

The Council reviewed a recommendation made by a delegate during the 2014 session of the ASHP House of Delegates, suggesting that ASHP create a guidance document articulating medication-use safety educational needs to schools and colleges of pharmacy, and further suggesting that the core competencies for a medication safety officer role should be linked to the pharmacy curriculum and to postgraduate training.

Extensive medication-use safety resources are available through ASHP's website and the Institute for Safe Medication Practices. Given the abundance of existing material on this subject, the Council believed an additional effort to develop guidance is not needed for faculty and preceptors of schools and college of pharmacy in order to adequately educate and train undergraduates.

The Council also noted that the medication safety aspect of pharmacists' responsibilities is rapidly evolving. ASHP should ensure that its website resources on this subject are updated and sustained in a current fashion. Possibly a section advisory group could be tasked to identify or create and maintain updated resources for the website.

The Council also reviewed a recommendation made by a delegate during the 2014 session of the ASHP House of Delegates, suggesting that ASHP create a new policy to advocate that schools and colleges of pharmacy should emphasize, in didactic and experiential education, instruction about achieving patient safety throughout the medication-use process.

The recommendation was made after the House of Delegates discontinued policy 0914, which read:

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

The House of Delegates discontinued the policy, believing that the matter is already addressed by schools and colleges of pharmacy. The topic is addressed in the CAPE outcomes and in the [Draft 2016 Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree](#). The Council concluded that a new policy was not needed.

## Continuing Pharmacy Education about Medication-Use Safety

The Council reviewed a recommendation made by a delegate during the 2014 session of the ASHP House of Delegates, suggesting that ASHP create policy for ongoing continuing pharmacy education about medication-use safety similar in style to ASHP policy 1317, Education and Training in Health Care Informatics, which reads:

To recognize the significant and vast impacts of health-system information systems, automation, and technology changes on safe and effective use of medications; further,

To foster, promote, and lead the development of and participation in formal health care informatics educational programs for pharmacists, pharmacy technicians, and student pharmacists.

The Council noted ASHP's longstanding, extensive commitment to continuing education about medication-use safety, including conferences devoted entirely to the subject in conjunction with the ASHP Summer Meetings. The Council believed that a policy was not needed to continue this commitment. The Council believed, however, that ASHP should find ways to provide resources or guidance to preceptors (e.g., through the ASHP [Patient Safety Web](#)

[Resource Center](#)) to help them better accomplish education of students and residents with respect to medication-use safety. This topic could be addressed in the next ASHP National Pharmacy Preceptors Conference.

Among the ideas that preceptors should convey are:

- safety is a systemwide issue; while medication-use safety is an important aspect of that subject, pharmacists should understand that their efforts are interwoven with the overall system's focus on patient safety;
- pharmacists must be able to articulate safety issues; and
- pharmacists must be able to advocate with others about needed actions.

Tools to assist preceptors would be useful, especially if posted on the ASHP Patient Safety Web Resource Center. Pharmacy is not the only health profession that must provide experiential education about patient safety. ASHP might be able to partner with other professional groups with respect to precepting on this subject. When or if those partnerships are established, ASHP should inform members that they exist.

## Simulation in Pharmacy Education

The Council reviewed a recommendation made by a delegate during the 2014 session of the ASHP House of Delegates, suggesting that ASHP create policy about the use of simulation in pharmacy curricula and continuing pharmacy education on the subject of medication-use safety. The delegate noted that simulation is a safe and effective means for training students and others in complex and unsafe situations, and the model developed by aviation seems to be ignored or limited in pharmacy education.

ACPE's [Draft 2016 Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree](#) include simulation as an approved education method, particularly in introductory pharmacy practice experiences. Mindful that pharmacy educators have the best expertise to choose and apply educational methods, the Council believed ASHP should not develop policy about the methods that schools and colleges of pharmacy should use.

## Quality Improvement

The Council reviewed a recommendation made by a delegate during the 2014 session of the ASHP House of Delegates, suggesting that ASHP encourage schools and colleges of pharmacy to include, in didactic and experiential education, instruction about quality improvement as applied to medication-use processes, and to support the development of postgraduate training (e.g., continuing pharmacy education, webinars, and conventions) to foster an increased number of pharmacists having quality improvement expertise. The Council examined ACPE's [Draft 2016 Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree](#). The Council noted that quality improvement is among the required elements of advanced pharmacy practice experiences and is addressed in the CAPE outcomes. Therefore, the Council believed it is not necessary to further encourage the

schools and colleges of pharmacy to address this topic.

The Council noted, however, that consistent with ASHP policy 0202, Performance Improvement, ASHP should consider creating comprehensive and repeated continuing education (live or electronic) about quality improvement for frontline practitioners. Policy 0202 reads:

To encourage pharmacists to establish performance improvement processes within their practice settings that measure both operational and patient outcomes; further,

To encourage pharmacists to use contemporary performance improvement techniques and methods for ongoing improvement in their services; further,

To support pharmacists in their development and implementation of performance-improvement processes.

*Performance improvement* and *quality improvement* are sometime used interchangeably, although they are not precisely the same ideas. The Council suggested that the Council on Pharmacy Management re-evaluate policy 0202 to consider incorporating the idea of quality improvement. The Council believed that frontline practitioner competence in quality improvement is essential to achieving the goals of the Pharmacy Practice Model Initiative.

## Work Realities in Experiential Education

The Council reviewed a recommendation made by a delegate during the 2014 session of the ASHP House of Delegates, suggesting that ASHP should work with ACPE, colleges of pharmacy, and other key stakeholders to require a portion of experiential education hours be gained outside normal business hours (e.g., outside typical day-shift hours, Monday-Friday) to help create more realistic expectations about employment environments that will be encountered upon licensure as pharmacists.

The Council concurred that, during experiential education, students should see and experience all work shifts. Preceptors have the freedom to assign students to night and weekend shifts for learning, provided adequate precepting is available at those times. How preceptors handle this likely will vary substantially across settings. ASHP could provide guidance to preceptors about this, through the ASHP National Pharmacy Preceptors Conference or published and online resources. An editorial, commentary, or letter to the editor in *AJHP* on this subject authored by a practitioner, an academic, and a student would be helpful.

## Education, Training, and Resources to Prepare Pharmacists for Scope of Practice Expansions

The Council noted that progress is occurring with respect to achieving provider status under Medicare rules by amending section 1861(s)(2) of the Social Security Act to enable reimbursement for pharmacists' clinical services. Scopes of practice for pharmacists are decided at the state level and likely will evolve further following the attainment of Medicare provider

status. Several states, including California, New Mexico, North Carolina, and Washington have (or are) already adopted(ing) expanded scopes. Details have not yet evolved about whether, in these developments, specific credentials or qualifications will be stipulated for pharmacists who engage in expanded roles.

Some advanced credentials exist already, including accredited residency training and certification by the Board of Pharmacy Specialties (BPS). However, not all pharmacists wishing to expand their roles will have or be able to obtain those credentials. The Council believed that, as the scopes of practice change, it will be important for ASHP to provide timely education and training for pharmacists to take on those expanded roles. The Council strongly urged ASHP to (a) begin now to develop scope guidance (perhaps to include model statutes and regulations or a menu or “catalog” of potential scope changes) for the states consistent with the [ASHP Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems](#) and (b) begin now to develop education and training based on best estimate about how the scopes are likely to evolve.

The Council suggested that ASHP consider (1) conducting a documented task analysis of pharmacists working already at an expanded level, (2) identifying the things practitioners need to know to practice at that level, (3) performing a gap analysis to determine the things that average health-system pharmacists do not know in list “2,” and (4) then developing education and training to address the gaps.

The Council acknowledged that accomplishing these things is bigger than the role of the Council alone. ASHP may need to create some sort of rapid-action task force to design and do all that is required. The Council noted that, in the absence of ASHP education and training, others will attempt to provide it. Without guidance from ASHP, it is possible that state policymakers will assume that the current level of pharmacist preparedness is the level of education and training to be anticipated going forward, and change scope provisions to conform to that level. If ASHP aspires to scope expansions and the specification of higher levels of education, training, or credentials in those expansions, there is some urgency to proceed with the necessary education and credentialing. Members should be helped to understand that these developments are consistent with the ASHP Pharmacy Practice Model Initiative, and they should be informed of the plans as soon as possible.

## Diversity in the Health-System Pharmacy Workforce

In the 2014 session of the House of Delegates, policies ASHP 0314 and 0409 were superseded by policy 1414. Policy 0314 read:

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

Policy 0409 read:

To foster awareness of the cultural diversity of health care providers; further, to foster recognition of the impact that cultural diversity of health care providers may have on

the medication-use process; further, to develop the cultural competence of pharmacy practitioners, technicians, students, and educators.

Policy 1414 reads:

To promote the development of cultural competency of pharmacy educators, practitioners, residents, students, and technicians; further, to educate providers on the importance of providing culturally congruent care to achieve quality care and patient engagement; further, to foster awareness of the impact that an ethnically and culturally diverse workforce has on improving health care quality.

After policy 1414 was approved by the House of Delegates, a delegate introduced a recommendation that ASHP return ASHP policy 1414 to the Council for revision to recognize the important distinctions between cultural competence and an ethnically diverse workforce. The delegate noted that cultural competence in patient care and diversity in the workforce has commonalities. However, there is a distinction between working with professionals of differing ethnic or religious backgrounds vs. the barriers frequently encountered with language, health literacy, health-care seeking behavior, and other cultural practices that affect patient-provider relationships. The delegate noted that it was the intent, in the Report of the ASHP Ad Hoc Committee on Ethnic Diversity and Cultural Competence (*Am J Health-Syst Pharm.* 2005; 62:1924–30), that these be recognized as distinct issues and that both should be addressed.

The Council carefully considered the history outlined above, the report of the ad hoc committee, the content of the revised policy, and the [ASHP Statement on Racial and Ethnic Disparities in Health Care](#), which was approved in 2007. The Council acknowledged that, among its recommendations, the ad hoc committee recommended the creation of policy about cultural competence and health disparities. The Council believed that the ASHP policy 1414 and the statement fulfill that intent and that there is no need for further policies or revision of policy 1414 at this time.

While the Council believed that further policies and revisions are not currently needed, they recommended ongoing attention to this subject. The Council believed that ASHP should more actively pursue and monitor diversity data about the health-system pharmacy workforce and ASHP's membership. Comparison data with respect to medicine and nursing would be helpful as well. Such data might reveal opportunities for further policies and actions. The Council recommended that such data be collected and reviewed annually as a standing agenda item.

## Pharmacy Student Debt

The Council discussed implications for pharmacy education and the health-system workforce in light of the following:

- In 2011, the average indebtedness for pharmacy students (\$114,422) was greater than the average first-year salary (\$112,160).
- Pharmacy students' total debt increased 23% in the five years preceding the analysis, compared to only 4.7% and 8.5% for medical and dental students.

The Council believed ASHP should develop plug-and-play programming to help educate students about their pending financial realities – programming that could be delivered through student societies in colleges of pharmacy, possibly by members of ASHP’s affiliated state societies. ASHP or the ASHP Research and Education Foundation should consider offering scholarships for academic expenses or attendance at ASHP meetings. ASHP should also consider developing a student loan resource center on its website, including an online tool to help students understand the financial realities of incurring debt.

## ASHP Expenses for Students

As an item of new business and related to the issue of student debt, the Council believed ASHP must be mindful that students are the profession’s future practitioners, and ASHP desires their loyalty as future ASHP members. In that respect, ASHP should consider the collective expenses that residency applicants incur, including expenses necessary to seek residencies (e.g., PHORCAS™, the cost of attending the ASHP Midyear Clinical Meeting to engage in residency showcases, Personnel Placement Service fees, interview expenses, and expenses that may be required to seek an unmatched residency position).

These expenses are in addition to expenses for travel, lodging, and food during the Midyear Clinical Meeting and for the North American Pharmacist Licensure Examination and licensure. The total financial burden for students (especially for those seeking residencies) is substantial. ASHP should find ways to communicate to students that they need to plan ahead for the expenses, particularly if they are seeking residencies. ACCP provides subsidies for some students to attend meetings. Staff noted that ASHP annually reviews all of its own fees and that the Council’s suggestions will be shared at that time.

## ASHP Ambulatory Care Summit

The Council reviewed several recommendations from the ASHP Ambulatory Care Summit conducted in March 2014. Overall, the Council believed there is much to be done to accomplish the recommendations in the summit report. The specific summit recommendations reviewed were 1.1, 1.4, and 2.7.

Recommendation 1.1 reads:

To provide optimal patient-centered care, pharmacists who provide ambulatory care services must attain and maintain appropriate competencies and credentials. Competency (as reflected, for example, in the eligibility requirements for sitting for the Board of Pharmacy Specialties in Ambulatory Care) is attained through training or commensurate experience.

Various credentials that are relevant were listed as eligibility qualifiers in the summit recommendation. The Council noted that ASHP policy 1415 is relevant and reads:

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

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

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

While a specific new policy saying the same thing specifically in relation to ambulatory care could be developed, the Council believed this was not necessary. ASHP already has developed guidance about entry-level competencies needed for ambulatory care practice. It is available on the ASHP website, but the Council suggested it be reexamined for currency, made easier to find, and have a date added to it. The Council cautioned that very detailed competency lists could serve as a barrier to some in the event that Medicare provider status is achieved for pharmacists practicing in ambulatory care.

Recommendation 1.4 reads:

There must be an increase in the number of ASHP-accredited residency positions offering training in ambulatory care and other training experiences in ambulatory care in order to ensure appropriately trained pharmacists to meet the needs of patients, providers, health systems, and payers.

The Council noted the existence of policy 0917, which reads:

To continue efforts to increase the number of ASHP-accredited pharmacy residency training programs and positions available.

The Council noted that ambulatory care is present in PGY1 residencies. BPS now certifies ambulatory care pharmacy specialists. The Council noted the existence and growth of PGY2 residencies in ambulatory care as well as ASHP's plans to expand all residencies and streamline accreditation standards and processes. Although the Centers for Medicare and Medicaid Services (CMS) does not authorize pass-through funding for sites that conduct PGY2 residencies, such programs continue to grow. ASHP could provide assistance by developing guidance about justifying PGY2 residency programs. The Council believed that the engagement of pharmacists in high-quality ambulatory care associated with health systems will grow faster than the growth of residencies. ASHP should be prepared to offer substantial ambulatory care continuing education, especially for pharmacists unable to enroll in ambulatory care residencies.

Recommendation 2.7 reads:

To promote efficiency and improve access to patient care, pharmacists who provide ambulatory care services should optimize the role of certified pharmacy technicians and other members of the healthcare team.

The Council noted the substantial role ASHP has played in accrediting pharmacy technician training programs, developing a model curriculum for pharmacy technician training (also endorsed by other organizations), leading the development of two white papers (with other

organizations), recently partnering with ACPE to establish joint accreditation of training programs, development of the [ASHP Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems](#) (which addresses the roles of both pharmacists and pharmacy technicians), and establishing PTCB.

The Council acknowledged the existence of the [Pharmacy Technician Web Resource Center](#) and ASHP policy 0702, which reads:

To support the goal that pharmacy technicians entering the pharmacy workforce have completed an ASHP-accredited program of training; further,

To encourage expansion of ASHP-accredited pharmacy technician training programs.

The Council believed ASHP is well engaged in fostering a highly qualified pharmacy technician workforce for ambulatory care and other health-system work.

## ACPE Draft Standards for Doctor of Pharmacy Degree Programs

The Council reviewed ACPE's February 3, 2014, [Draft 2016 Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree](#). The draft standards are out for comment until December 2014. The Council found the draft mostly appropriate and provided ASHP staff with suggestions for comments to submit to ACPE.

## BPS Specialty Structure and Framework

The Council discussed the July 2014 [BPS Pharmacy Specialty Structure and Framework Discussion Paper](#). The Council believed the paper did not sufficiently document any societal need that would be addressed by creating subspecialties. The Council was also concerned about worsening the already somewhat complex array of pharmacists' credentials and the expense (to individuals and ultimately to employers) that would be required to sustain subspecialties. The Council believed the approach would be difficult, if not impossible, to administer in a sound financial way. The Council also believed that the creation of subspecialties in areas such as oncology or pediatrics would require the development of PGY3 residency training to be successful and was concerned that the development of such programs would further strain the capacity of practice sites to meet current demand for PGY1 and PGY2 residency programs.

BPS should consider carefully what the "sub" syllable would convey to employers and the public. BPS can be commended for contemplating potential new structures in specialization, and it could evolve that aspects of what BPS has proposed might have merit in the future. However, the Council believed that it is not needed or wise to create formal subspecialties at present. BPS would be better advised to grow the number of individuals certified as specialists.

## Credentialing and Privileging of Pharmacists

The Council reviewed the 2014 resource paper [Credentialing and Privileging of Pharmacists](#) by the Council on Credentialing in Pharmacy (CCP) and provided the ASHP staff with comments to

consider providing to CCP about the paper.

A search for the word “credentialing” at the main ASHP website revealed 382 documents on that subject. Some of the documents reside in the Section’s web pages. Since that topic is applicable to many sections and forums, as well as other arenas of ASHP’s interests and activities, ASHP should consider creating a distinct resource center on credentialing and privileging. Items about credentialing and privileging that now appear only in the Section’s web pages should still be listed there as well. It would be useful to list in the Section’s web pages information from CMS about its broadened concept allowing hospitals the flexibility to include nonphysician practitioners as eligible candidates for the medical staff with privileges to practice in the hospital under the hospital’s rules for the medical staff and in accordance with state laws.

## Distinction between Actions and Policies

As an item of new business and stimulated by its discussion of policy 0509, which is long and has many components, the Council noted that it is often appropriate for a policy to express an intent or a wish to take some action. However, it is wise to be mindful of the distinction between a to-do action list versus an expression of policy. The Council was assisted in its deliberations by a list of potential actions, other than policy formation, that the Council could suggest. The Council believed that regional delegates’ conferences (RDCs) provide a good opportunity to review with delegates the roles of the Board and the House and the distinctions between actions and policies. The Council believed that the list of potential actions (other than policy formation) would be useful at the RDCs and in the delegate work room at the Summer Meetings.

## Multidisciplinary and Interprofessional Residencies

As an item of new business, the Council reflected on the need for pharmacists to be educated and trained in a multidisciplinary and interprofessional fashion. The Council noted an idea in the [ASHP Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems](#) that residencies enrolling residents from multiple professions could evolve. While this seems speculative, and barriers to development can easily be envisaged, the Council suggested that the idea be placed on its 2015 meeting agenda. ASHP has discussions scheduled to confer with the accrediting body for nursing residencies and the Accreditation Council for Graduate Medical Education to explore ways to collaborate. One possibility is for nurses to be preceptors for some pharmacy experiences and pharmacists to be preceptors for some nursing experiences.

## Education and Training for Pharmacy Technicians to Assume Advanced Roles

As an item of new business, the Council reflected on the hope and goal that nonpharmacists will increasingly handle and will eventually manage as well as carry out drug preparation and distribution, while pharmacists will be engaged in direct patient care. Consistent with observations in the [ASHP Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems](#) that configuration of the workforce will require very highly qualified pharmacy

technicians and possibly high-level nonpharmacists (perhaps individuals with degrees in relevant fields such as logistics) who also will have completed pharmacy technician training. Importantly, the desired competencies for advanced roles have not been systematically defined, and no education and training programs exist for generating such individuals. If ASHP seeks such individuals, a major effort will be required. Task analyses may be needed, job responsibilities will have to be defined, and educational programs will have to be developed (possibly with a model curriculum). A credential may have to be developed for the most qualified people. Quality improvement will have to be among the knowledge and skills of such people, including not just carrying out quality improvement activities but actually conceptualizing, planning, and launching the activities and having the authority to modify work procedures to adapt to quality improvement findings. Similarly, if these people are to be responsible for managing as well as carrying out the preparation of sterile products, appropriate knowledge and skills will have to be taught.

There is an analogy in this to the approach hospital pharmacy took more than 60 years ago. Hospital pharmacy faced up to the reality that colleges of pharmacy could not possibly completely educate and train all students to be the highly competent pharmacists needed for hospital pharmacy practice. Therefore, residencies were created. It was a transformational decision, and it helped hospital and health-system pharmacy to become what it is today. Passing medication preparation and distribution to nonpharmacists also would be transformational. The Council believed it should discuss this topic at a future meeting with an aim to define where the profession wants to go and contemplate what it will take to make it a reality.

## **Nontraditional Advanced Pharmacy Practice Experience (APPE) Schedules**

The Council reviewed progress on advocating for nontraditional APPE schedules and agreed to continue to monitor progress at future meetings.



pharmacists advancing healthcare

# House of Delegates

## Board of Directors Report on the Council on Pharmacy Management (Final)

*The Council on Pharmacy Management is concerned with ASHP professional policies related to the process of leading and directing the pharmacy department in hospitals and health systems. Within the Council’s purview are (1) development and deployment of resources, (2) fostering cost-effective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.*

### Council Members

- Karl Kappeler, *Chair* (Ohio)
- Michael Nnadi, *Vice Chair* (North Carolina)
- Sam Calabrese (Ohio)
- Debra Cowan (North Carolina)
- Bonnie Kirshenbaum (Colorado)
- John Lewin (Maryland)
- Christine Marchese (Rhode Island)
- Tricia Meyer (Texas)
- Brandon Ordway (Minnesota)
- Roger Woolf, (Washington)
- Rusol Karralli, *New Practitioner* (Texas)
- Kelly Sennett, *Student* (Minnesota)
- David Chen, *Secretary*

Don Letendre, *Board Liaison*

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*(Click on title to view section)*

## Policy Recommendations

### 1

### Impact of Insurance Coverage Design on Patient Care Decision

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

(Note: This policy would supersede ASHP policy 1017.)

#### **Rationale**

Evolving practices by health insurers are affecting patient care decisions in hospitals and health systems. One increasingly common health insurance practice restricts management of and access to certain drugs to specialty suppliers, which may coincide with a particular drug being shifted from a medical benefit to a prescription benefit. 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. In turn, hospitals and health systems often make determinations differently on how to manage billing for these drugs, causing compliance concerns and customer service challenges. Pharmacy leaders are charged with ensuring the safe use of medications, regulatory compliance, and customer satisfaction in an environment that is increasingly making insurance coverage decisions that do not take into consideration the hospital and health-system patient care environment. Billing patients for these medications can result in public relations challenges, especially when other facilities in the same service area elect not to charge for SADs. Failing to bill can result in compliance concerns, and verifying and documenting the integrity of patients’ medications can be time consuming and is particularly challenging when treating patients in emergency departments and observation units.

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 hospitals and health systems. In the case of high-cost injectable medications, which can be difficult to identify, providers and patients may face difficult decisions about delivering care. It is the responsibility of the pharmacist to ensure the integrity of drugs used in the care of patients in the health care facility in which he or she practices. Patients bringing their own medications from multiple suppliers that require verification disrupts the care process. Having patients go unreimbursed for product because it was administered in and supplied by the hospital or health system 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.

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 at hospitals and health systems. In addition, ASHP advocates that the Centers for Medicare & Medicaid Services (CMS), 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 policy 1017, Impact of Insurance Coverage Design on Patient Care Decision, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate that all health insurance policies be designed and coverage decisions made in a way that preserves the patient-practitioner relationship; 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 ~~exclusion~~ of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients. ~~settings from restrictive reimbursement requirements.~~

The Council discussed the changing insurance and coverage determination environment in the U.S. healthcare marketplace. Insurance requirements have been addressed in past ASHP policy, but as pharmacy leaders increasingly engage in supporting their organizations expansion into ambulatory care environments the contracting side of insurance design has made it difficult to provide continuous care for health systems.

As aspects of the Affordable Care Act (ACA) have been implemented, health systems have had to make decisions on how to handle issues like charity care and its interplay with insurance coverage requirements. In some cases, health systems have been locked out of accessing patient populations when their system was not included in a previous network, presenting a

potential loss of large patient populations. The Council discussed how patients and providers increasingly have to navigate a complex financial matrix of payer and plan designs to access care, which can increase the number of providers patients need to see, negatively impact continuity of care, and prevent patients from using providers of their choosing, even for pharmacy prescription services.

The Council also considered concerns that with the continued development of Medicare Part D preferred provider networks large chain drugs stores will capture the entire market and prevent vital pharmacy services to underserved areas. Additionally, as health-system pharmacy leaders have sought to expand their ambulatory pharmacy operations or develop specialty pharmacy services they find there are exclusive provider agreements for certain patient segments or medications, preventing the health system from entering the marketplace and providing continuity of care for patients. These disruptions in care can lead to nonadherence with prescribed medications, increased hospital readmission, and increased cost of care.

The Council also discussed the importance of ASHP members being educated on accreditation necessary to meet payer requirements, as well as to how to advocate locally for inclusion in health-system contracts. Additionally, patients and providers need to have a strong understanding of the increasing requirements to access care and providers, as unnecessary loss of reimbursement or payment may result. The Council suggested ASHP consider methods to provide education and resources specifically addressing these insurance, contracting, accreditation, and reimbursement issues that are emerging in the market.

## 2

### Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs

- 1 To advocate that pharmacists ensure that the use of patient assistance programs is
- 2 optimized and documented to promote continuity of care and patient access to needed
- 3 medications; further,
- 4 To support the principle that medications provided through manufacturer patient
- 5 assistance programs should be stored, packaged, labeled, dispensed, and recorded
- 6 using systems that ensure the same level of safety as prescription-based programs that
- 7 incorporate a pharmacist-patient relationship.

(Note: This policy would supersede ASHP policy 0603.)

#### **Rationale**

Ensuring patients' medication histories are accurate and continuity of medication therapies is a critical role for pharmacists to monitor and document as patients transition through the healthcare system. Additionally, pharmacists have an important role in ensuring patients have means to access their medications, both upon hospital admission and discharge. With the

numerous channels patients use to obtain their medications, it has become increasingly difficult to verify this information and in some cases obtain the medications needed to care for a patient.

Patient assistance programs (PAPs) present a unique challenge for healthcare providers. Documentation of the utilization of a PAP by a patient is important information for providers accessing the patient electronic health record, and improving that documentation should be a priority for healthcare providers. Additionally, pharmacists need to provide leadership in facilitating the utilization of PAPs to ensure continuity of care and the patient's ability to access needed medications when appropriate.

### **Background**

The Council voted to recommend amending policy 0603, Medication Management for Patient Assistance Programs, as follows (underscore indicates new text):

To advocate that pharmacists ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist-patient relationship.

The Council discussed ASHP policies on patient assistance programs. It was felt the current policies did not address need to have proper PAP information in EHR (i.e. medication was actually being supplied by a PAP) and the pharmacist's responsibilities to facilitate obtaining PAP medications as part of the interdisciplinary team. The Council noted patient assistance programs are still very essential to health care and with changes in many PAP requirements pharmacists would need to have the knowledge necessary to provide appropriate medication therapy consultations and decisions to ensure patients maintained therapies through transitions between providers.

## 3

### **Disposition of Illicit Substances**

- 1 To encourage healthcare organizations to develop procedures for the disposition of
- 2 illicit substances brought into a facility by patients that ensure compliance with
- 3 applicable laws and accreditation standards; further,
- 4 To encourage healthcare organizations to include pharmacy leaders in formulating such
- 5 procedures.

**Rationale**

Hospitals and health systems often are faced with patients that have in their possession illicit substances (e.g., [Schedule I](#) drugs, or other illegal or illegally possessed substances), which requires the facility to make decisions about how to secure the substances, ensure the appropriate chain of custody, and document possession in the patient's medical record, as well as whether to inform law enforcement. These circumstances require the organization's legal counsel to make a determination for the organization, and pharmacy leaders are faced with deciding on their interpretation of the pharmacist-in-charge's legal requirements and related accreditation standards.

**Background**

The Council discussed the issue of how to respond when patients who have illicit substances in their possession are admitted to the hospital or health system's care. It was noted that these substances are not medications, and the Council concluded that they should be handled as any other illicit substance or item, such as a weapon. The Council recognized that in some cases the patient or hospital may legally access a Schedule I controlled substance for research purposes.

The Council discussed the importance of pharmacists being acutely aware of their particular states laws and regulations, as well as federal laws and regulations, pertaining to the particular classification of a substance that may have varying interpretations of illicit status.

The Council concluded that healthcare organizations should have a procedure or plan in place to address all illicit items in a similar manner, through the security processes of the organization, with the input of pharmacy leadership when appropriate.

**4****Pharmacist's Role in Population Health Management**

- 1 To recognize the importance of medication management in patient-care outcomes and
- 2 the vital role of pharmacists in population health management; further,
  
- 3 To encourage healthcare organizations to engage pharmacy leaders in identifying
- 4 appropriate patient cohorts, anticipating their healthcare needs, and implementing the
- 5 models of care that optimize outcomes for patients and the healthcare organization;
- 6 further,
  
- 7 To encourage the development of complexity index tools and resources to support the
- 8 identification of high-risk, high-cost, and other patient cohorts to facilitate patient-care
- 9 provider panel determinations and workload balancing; further,
  
- 10 To promote collaboration among members of the interprofessional healthcare team to
- 11 develop meaningful measures of individual patient and population care outcomes.

**Rationale**

As hospital and health systems become larger and adjust to new payment models (e.g., readmissions penalties and reduced Medicare payments), the need for health-system and pharmacy leaders to determine the safest, most efficient, and most economical way to care for identified patient populations has become a significant challenge. Pharmacists have an important role in managing medication therapies for individual patients as well as participating in the development of care models for patient populations with the interprofessional teams they work within. The utilization of “big data” by health systems is a growing domain of research, and it will be important for pharmacy leaders to make use of this information when developing strategic plans and resource allocations. Similar to the workload and productivity issues traditionally facing hospital leaders, the need to stratify total patient populations, anticipate their healthcare resource needs, and then assign the best site and model of care to obtain the ideal return on investment for both the patient and organization has become of paramount importance. The need for identifying the ideal patient panel sizes and the demographics of these panels will be important for patients and pharmacists as pharmacists practice more in the ambulatory care environment.

**Background**

The Council discussed the importance of pharmacists having a role in managing patient populations and the challenges associated with balancing individual patient-care needs and developing and implementing population health strategies. With dramatic increases in the number of Americans over 65, the number of people living longer with chronic disease, the number of people with chronic disease, and the increasing importance of medications as a significant modality for keeping patients healthy, there is a need for pharmacists to manage patient populations, and identify and manage high-risk and high-cost patients. The Council concluded that pharmacy needs to develop its role in improving population and patient management at all levels, including management of the insured and uninsured. Strategies should be developed to identify and stratify patients based on characteristics such as chronic disease, age, and utilization of resources, including the use of “big data” and predictive analytics to identify and manage high risk and high cost patients.

One thing adding complexity for pharmacy leaders as they develop and expand ambulatory care services is the need to concurrently address the population health strategies and patient panel determinations that provide the most improved patient-care and organizational outcomes. As noted in the Department of Veterans Affairs [VHA HANDBOOK 1101.10](#):

Population management refers to the use of data to address the health status of a cohort of patients defined by specific parameters. Population management of a patient panel means that population management strategies are used to assess and address the care needs of all patients assigned to the panel. Panel management refers to management of assigning patients to a panel and managing the panel size.

It is this interface of societal need and stewardship of health-system resources that provides the challenges to pharmacy leaders in seeking to develop or expand patient-care services, as well as ensuring the most appropriately trained pharmacists are positioned to care for a

particular population of patients. Additionally, pharmacy will need to develop and utilize measures that show the value of pharmacy while improving population health.

The Council also discussed the need for advanced education for pharmacy leaders on the principles of population health, where and how to access the necessary data to support decision-making, and information available on existing measures and outcomes management, accreditation, and reimbursement issues that are emerging in the market.

## 5

### ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

- 1 To approve the ASHP Statement on the Roles and Responsibilities of the
- 2 Pharmacy Executive ([Appendix](#)).

#### **Background**

The Council revised the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive approved in 2008 to reflect changes in the healthcare environment, most notably the increasing number of merger in large healthcare organizations.

## 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.)

- [Standardization of Medication Formulary Systems](#) (9601)
- [Pharmacy Staff Fatigue and Medication Errors](#) (0504)
- [Health-System Facility Design](#) (0505)
- [Pharmaceutical Distribution Systems](#) (1016)

## Other Council Activity

### Financial Management of the Pharmacy Enterprise in Current Healthcare Environment

The Council voted to explore the feasibility and benefits of ASHP creating and maintaining member resources to help ensure pharmacy leaders maintain financial management skills and have access to timely data to effectively lead the pharmacy enterprise; further,

To consider in this assessment: (1) needs assessment on types and level of resources and education for pharmacy leaders, (2) determination of best methods to obtain and interpret timely healthcare-finance-related information, (3) assessment of the information vehicles most useful and meaningful for pharmacy leaders to improve their abilities to manage the financial aspects of their pharmacy enterprises, and (4) best mechanisms to improve sharing of ideas and information to improve financial acumen of pharmacy leaders.

Healthcare finance and business management is becoming increasingly complex as healthcare reform evolves, markets and market partners change, demands of compliance with regulators and auditors intensify, and healthcare costs continue to grow as a percentage of GNP. Pharmacy leaders have a responsibility to continually advance pharmacy practice to improve patient-care outcomes and experiences as well as manage the financial complexities of pharmacy services. Being an effective financial steward of the organization's pharmacy enterprise requires skillsets ranging from understanding the continuous stream of updates and changes in payment and contracting to understanding the healthcare financing environment to position pharmacy to be successful and support the healthcare organization's goals and mission.

The Council discussed the ASHP policies, statements, and guidelines related to healthcare finance and financial management and felt the documents covered the necessary components to advocate for and guide pharmacy leaders and health-system pharmacy. The Council noted the need to finalize guidance on revenue cycle management.

## **Professional Policy Considerations for Clinics and Other Ambulatory-Based Pharmacy Practice Settings**

The Council voted to suggest ASHP aggregate all the relevant ASHP policies, statements, and guidelines associated with each ASHP Ambulatory Care Summit recommendations. The Council also voted to explore the development of metrics that support ASHP Ambulatory Care Summit recommendations.

Health systems and healthcare in the United States are highly focused on reducing hospital admissions and treating patients in lower-cost ambulatory care settings. With dramatic increases in the number of Americans over age 65, the number of people living longer with chronic disease, the number of people with chronic disease, and the increasing importance of medications as a significant modality for keeping patients healthy, patient-care settings in ambulatory care are growing, with gross hospital inpatient revenues shifting to outpatient revenues.

The Council discussed the integral role pharmacists have in managing patients in the ambulatory setting. Pharmacists aid in obtaining quality outcomes and improving quality of life for patients, and improve clinical and economic outcomes. However, there is still a need to proactively establish practice models that demonstrate these benefits, including the maintenance and establishment of sustainable business models and reimbursement mechanisms.

## Management of Charge Description Master Affecting Medication Use

The Council discussed the challenge of identifying and selecting appropriate standards and methods for health information management and, more specifically, the pharmacy charge description master. Since the introduction of technology into the healthcare system, the importance of maintaining up-to-date databases and patient data has only increased. To assure quality and safety, the information available for healthcare providers should be both current and accessible at the right time to support patient care, as well as accurately maintained and documented in order to obtain proper reimbursement for care provided. However, there is still a lack of consistency among hospital databases and the timelines needed to ensure that medication-related records are current.

The Council discussed the need for specific guidance and resources for pharmacy leaders to effectively manage and understand the complexities of medication charge master description management. Specifically, the Council discussed the urgency to finalize a statement on revenue cycle management as well as create related education and resources. The Council suggested the Section of Pharmacy Informatics and Technology further define and delineate payment, compliance, integrity, and patient-safety issues related to management of the pharmacy charge description master, and determine whether ASHP policy and/or resources are needed to support best practices. The Council noted a document addressing pharmacy charge description master would be synergistic with existing ASHP policies addressing harmonization of patient-care technologies and risk assessment of health information technologies.

## Compliance and Regulatory Management and Expansion of Regulators Scope of Influence

Hospitals and health-system pharmacy leaders have years of experience in managing the demands and challenges of ensuring pharmacy services meet the standards of accreditation organizations. In order to be a qualified provider for CMS, hospitals need to be certified and meet the standards of an approved accreditation organization, or by the CMS state-based survey process. Until recently this accreditation was predominantly through The Joint Commission (TJC). Hospitals with additional ambulatory care services such as home infusion and durable medical equipment also have to manage the accreditation process for these business units. If a hospital is TJC accredited they are required to have the nonhospital-based business units surveyed by TJC if TJC has a corresponding accreditation process.

Until recently the market was fairly narrow, with only a few accreditation organizations hospital and health-system pharmacy leaders needed to be knowledgeable about. Three phenomenon in the past few years have created challenges for pharmacy leaders: (1) TJC is no longer the only accreditor for hospitals and health systems; (2) health systems are building or acquiring new business units, which have their own accreditation processes that need to be integrated into those of the health system; and (3) new accreditation processes have been established or are being established in the marketplace for businesses that pharmacy leaders may be responsible for or are considering undertaking.

It was suggested ASHP should evaluate the accreditation environment and assess its advocacy to drive for more outcomes-based processes.

## Council Statement and Guidance Proposal Review

The Council reviewed the outstanding statement and guideline proposals. The Council decided to establish a separate work group to review the minutes of the Council that proposed the creation of the outstanding guidelines and statements to aid in their determination of which proposals to maintain or eliminate. The Council discussed the process and resources needed to accomplish the completion of these documents. The Council voted to continue development of the following guidance documents:

- ASHP Statement on Revenue Cycle Compliance and Management,
- ASHP Guidelines on Selecting Pharmaceutical Manufacturers and Suppliers, and
- ASHP Guidelines on Recruitment and Retention of Pharmacy Personnel

and to discontinue development of the following guidance documents:

- ASHP Guidelines on Coordinating Care with Specialty Pharmacy Services,
- ASHP Guidelines on Pharmacist Privileging and Credentialing in Hospitals and Health Systems,
- ASHP Guidelines on Effective Use of Consultants within the Pharmacy Enterprise,
- ASHP Guidelines on Recalls of Drug Products and Medication-Related Devices, and
- ASHP Guidelines on Emergency Management Planning.

## Specialty Pharmacy

The Council reviewed ASHP policy on various aspects of specialty pharmacy and agreed to add it to future agendas. The Council discussed the need for ASHP to consider an in-depth analysis of the supply chain in light of the emerging challenges facing health-system pharmacies. One of those challenges is ensuring seamless patient care in light of the free-market medication supply chain's inability to guarantee timely access to the necessary medications.

# Appendix

## ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

### Executive

#### Position

- 1 The American Society of Health-System Pharmacists (ASHP) believes that complex hospitals and
- 2 health systems benefit from having a pharmacy executive responsible for the strategic
- 3 planning, design, operation, and improvement of their organization's medication management
- 4 system. This individual (sometimes referred to as the "chief pharmacy officer" but hereafter
- 5 "the pharmacy executive") must be properly positioned within the organization to ensure the
- 6 best utilization of his or her expertise in all decisions regarding medication management. To
- 7 promote effective communication, collaboration, and teamwork with peers, the pharmacy
- 8 executive should

- 9 • Have a title internally consistent with others reporting at that organizational level,
- 10 • Report directly to the organization’s principal executive (e.g., chief executive officer
- 11 [CEO], chief operating officer [COO]),
- 12 • Be involved in the organization’s strategic planning regarding all components of the
- 13 medication management process across the continuum of care,
- 14 • Participate in regularly scheduled healthcare executive-level meetings, (e.g. CEO, COO,
- 15 chief financial officer [CFO], chief medical officer [CMO], and chief nursing officer [CNO]),
- 16 • Be a member of the medical executive committee (or its equivalent), and
- 17 • Engage in regular, direct communication with health system leadership and the board of
- 18 directors about medication management system performance.

### Background

19 Hospitals and health systems are complex organizations. Executive-level decisions that affect  
20 the medication management system are made at a rapid pace, often with profound im-  
21 plications for patient care, patient safety, and the health system’s fiscal well-being. The  
22 pharmacy executive must be properly positioned within an organization to ensure the best  
23 utilization of his or her expertise in decision-making that affects the policies, procedures, and  
24 systems that support safe, effective, and efficient medication management. The quality and  
25 timeliness of information exchange improves significantly when pharmacy leadership reports  
26 directly to the principal executive rather than through multiple layers of management.  
27 Pharmacy leaders can more actively engage in critical decision-making and will be more effec-  
28 tive in helping the health system anticipate and address rapid change.

29 Significant changes in pharmacy practice, healthcare, and health-system management over  
30 the past 20 years have dramatically transformed the traditional role of the pharmacy director.<sup>1</sup>  
31 More widespread use of the title “chief pharmacy officer” was first proposed in 2000 in an  
32 attempt to enhance the contribution pharmacy makes to patient care by creating  
33 organizational parity between the pharmacy executive and other chief officers (e.g., chief  
34 nursing, medical, and information officers).<sup>2</sup> When the pharmacy executive works col-  
35 laboratively with others at this executive level, the pharmacy department is better positioned  
36 to effectively contribute to the organization’s strategic initiatives and address system-wide  
37 issues regarding medications and medication management.

### Qualifications and Responsibilities of the Pharmacy Executive

38 The pharmacy executive is a professionally competent, legally qualified pharmacist. He or she  
39 must be thoroughly knowledgeable about and have experience in hospital pharmacy practice  
40 and management. Additional qualifications might include completion of a pharmacy residency  
41 program accredited by ASHP, an advanced management degree (e.g., M.B.A., M.H.A.), or an  
42 administrative specialty residency.

43 What distinguishes the pharmacy executive from the established director of pharmacy position

44 is a deeper knowledge of the organization's operations as well as a greater degree of  
45 involvement in the organization's strategic planning and decision-making processes. The  
46 pharmacy executive provides the organization with pharmacy's unique clinical and business  
47 perspectives in discussions and decisions related to changes in the medication management  
48 system.<sup>3</sup> He or she has experience leading evidence-based clinical decision-making about drug  
49 use, controlling pharmaceutical expenses while maximizing patient benefit through the  
50 formulary system. The pharmacy executive has in-depth knowledge of the pharmaceutical  
51 supply chain, clinical therapeutics, physician prescribing habits, medication management  
52 systems, medication-use policy, and the technology used to deliver and support patient care  
53 and about how those issues affect the overall success of the organization. The pharmacy  
54 executive understands the relationships between third-party requirements, coding,  
55 documentation, billing equations, pricing updates, and organizational resources and can  
56 provide quality assurance for all these functions, improving financial performance.<sup>4</sup>

57 The pharmacy executive's responsibilities include but are not limited to the following: strategic  
58 planning; designing, managing, measuring and improving the medication management system;  
59 ensuring quality outcomes through performance-improvement activities; leading drug-  
60 utilization efforts; optimizing use of information systems and technology; managing the  
61 pharmaceutical supply chain, pharmacy department financial operations, and human resources;  
62 ensuring compliance with regulatory and accreditation requirements; fulfilling the  
63 organization's research and educational missions; and providing institutional representation  
64 and leadership.<sup>5,8</sup> The pharmacy executive fulfills these responsibilities through his or her own  
65 actions, proper delegation to competent individuals on his or her staff, and collaborative efforts  
66 with other healthcare professionals.

67 **Strategic Planning.** The pharmacy executive assesses the ever-changing healthcare  
68 environment for emerging trends that will influence the pharmacy enterprise. He or she  
69 identifies opportunities to leverage pharmacy expertise to improve quality, safety, patient  
70 experience, access across the continuum of care and the economic performance of the  
71 organization. It is also the pharmacy executive's responsibility to continually assess healthcare  
72 related trends and discoveries to ensure the value of pharmacy and pharmacists is advocated  
73 for and advanced in overall efforts to improve patient care<sup>6,7</sup>.

74 **Optimizing Medication Management and Advancing Pharmacy Practice.** The pharmacy  
75 executive is responsible for ensuring that pharmacists participate as the interdisciplinary team  
76 members who are responsible for patients' medication-related outcomes. He or she ensures  
77 that pharmacy is responsible for developing and ensuring compliance with evidence-based  
78 prescribing criteria that support effective, safe and fiscally responsible treatment. The  
79 pharmacy executive will ensure collaboration outside of the walls of the institution, fostering  
80 pharmacist communication with patients and outpatient providers following discharge to  
81 ensure continuity of medication therapy and monitoring of patient outcomes. With the  
82 expanded role of the pharmacist in drug therapy management, he or she is responsible for the  
83 professional development of the pharmacy team in order to support this advanced role.

84 **Advancing the Application of Information Technology in the Medication Management**

85 **System.** The pharmacy executive provides leadership at the organizational level regarding  
86 planning, purchasing, implementing and maintaining information systems that support patient  
87 care. He or she is responsible for the adoption of a long-term perspective and commits  
88 themselves to achieving the patient-safety innovations made feasible by Electronic Health  
89 Records (EHRs) and other clinical applications: Computerized provider order entry (CPOE),  
90 clinical decision support (CDS), automated medication reconciliation, bar-coded medication  
91 administration (BCMA), medication surveillance, telepharmacy, and smart infusion pumps. The  
92 pharmacy executive will leverage technology to advance pharmacist clinical practice through  
93 implementation of processes that allow pharmacist work load to be more heavily devoted to  
94 patient-care activities and ensuring that the EHR supports drug therapy management services.  
95 He or she will leverage technology capabilities to improve the safety of medications, specifically  
96 those identified as high-risk. The pharmacy executive will utilize technology enabled medication  
97 management data to capture and report pharmacy metrics and to drive improvements in  
98 patient care and outcomes. He or she will ensure CDS systems support processes for the  
99 enhancement of medication-related decisions and actions with pertinent, organized clinical  
100 knowledge and patient information to improve health and healthcare delivery. The pharmacy  
101 executive will ensure that appropriately trained and qualified pharmacy team members are  
102 available to safely develop, implement and maintain medication related technology. Use of  
103 technology to increase the safety and efficiency of medication distribution, including  
104 automated dispensing units (ADU), carousels, and compounding automation should also be  
105 leveraged.<sup>8</sup>

106 **Medication System Management and Improvement.** The pharmacy executive is responsible for  
107 overseeing the design, implementation, and management of a safe and effective medication  
108 management system. He or she ensures that systems are developed and improved based on  
109 evidence and best practices, operate effectively and efficiently across the continuum of care,  
110 and are continuously evaluated and improved using contemporary quality-improvement  
111 methods. The pharmacy executive provides leadership at the organizational level to ensure that  
112 pharmacists are positioned to improve the quality, safety and efficiency of medication  
113 management throughout the health system. The pharmacy executive (or his or her designee)  
114 should be a member of all of the institution's key committees responsible for performance-  
115 improvement activities related to medication management and patient safety. The pharmacy  
116 executive and his or her staff must be intimately involved in all improvement initiatives  
117 involving medication management. The pharmacy executive should give particular attention to  
118 patients in high-risk areas (as identified by organizations such as the Centers for Medicare and  
119 Medicaid Services, the Joint Commission and other accreditation organizations) to ensure that  
120 pharmacy services meet patient care needs and that drug therapy is as safe, effective, and  
121 economical as possible. Safe handling of hazardous medications throughout the medication  
122 process (preparation, administration, and disposal) is assured. The pharmacy executive is  
123 responsible for developing plans for the continued operation of medication management  
124 systems and for the provision of pharmaceutical services during emergencies and disasters.

125 **Quality Outcomes.** With a greater percentage of reimbursement being tied to quality  
126 outcomes, the pharmacy executive is responsible for leveraging pharmacy expertise in support  
127 of value based purchasing, including leading core measures initiatives involving medication

128 therapy, playing an active role in reducing readmissions, and owning the process for medication  
129 related customer satisfaction indicators. He or she will take steps to ensure that pharmacists in  
130 the department are highly skilled at communicating with patients through assessment of  
131 individual pharmacist competency in this area and implementation of professional  
132 development plans. The pharmacy executive will identify and implement specific ways that the  
133 pharmacy enterprise can contribute to the patient experience related to the care they receive  
134 at admission, during the stay and at discharge. He or she takes a leadership role in program  
135 development to reduce drug-related hospital readmissions through patient education about  
136 the appropriate management of medications, embedding pharmacy in the care transitions  
137 process and implementing programs such as medication history technicians and bedside  
138 delivery of discharge prescriptions. The pharmacy leader also commits to continuously improve  
139 the organizations medication reconciliation process at all care transitions.

140 **Drug-Utilization Management.** The pharmacy executive collaborates with peers to develop  
141 drug-utilization and formulary initiatives that optimize therapeutic outcomes, reduce the risk of  
142 drug-related problems, and ensure the use of cost-effective pharmacotherapy throughout the  
143 health system. The pharmacy executive ensures there is pharmacist representation on the  
144 pharmacy and therapeutics committee(s) of the health system as an active voting participant.  
145 He or she identifies inappropriate utilization and leads efforts to modify practices to improve  
146 medication management. The pharmacy executive (or a designee) is a member and active  
147 participant of the antimicrobial stewardship committee, anticoagulation, pain and other  
148 specialized teams to ensure that stewardship principles are applied to the prescribing,  
149 dispensing, and administration of these agents.

150 **Supply Chain Management.** The pharmacy executive is responsible for oversight of all  
151 pharmaceutical contracting, procurement, receiving, security, inventory control, diversion  
152 prevention, and distribution policies across the continuum, including outsourced sterile  
153 products, alternate distribution channels utilized during drug shortages, reverse distribution  
154 and other methods of pharmaceutical waste disposal. He or she ensures that the methods used  
155 to contract and obtain products are safe, cost-effective, and timely. The pharmacy executive is  
156 also responsible for emergency preparedness of the supply chain, including strategies to ensure  
157 ongoing safe and effective patient care during drug product shortages through the collaborative  
158 development of alternatives to treatment and restricted use guidelines.

159 **Financial Management.** The pharmacy executive manages the health-system pharmacy's  
160 financial performance within the context of the broader health system. He or she develops  
161 budgets aligned with organizational and departmental objectives and monitors financial  
162 performance appropriately, performing financial audits and analysis as needed to ensure  
163 accurate, appropriate, and timely recording and classification of actual revenue capture and  
164 expenses. The pharmacy executive evaluates medication expenditure patterns and  
165 reimbursement trends, including the potential development of value-based approaches to  
166 pharmaceutical reimbursement. He or she seeks opportunities to implement medication  
167 related services that can improve the financial health of the organization, such as retail  
168 pharmacy and ambulatory infusion. He or she ensures that the pharmacy department has the  
169 expertise to manage the clinical and financial implications of specialty pharmaceutical products.

170 The pharmacy executive may be called upon to provide guidance in areas outside of the  
171 traditional pharmacy arena, including management of drug expenditures in the self-insured  
172 employee population and in payer shared risk arrangements that include medication  
173 management incentives.

174 **Managing the Pharmacy Workforce.** The pharmacy executive manages the health-system  
175 pharmacy's workforce efforts. These efforts include determining the appropriate number, type  
176 and qualification of staff required to meet patient care needs, satisfy regulatory and accrediting  
177 requirements, achieve the organization's mission and advance pharmacy practice. In order to  
178 accomplish this task, he or she implements standards and development programs to advance  
179 the use of pharmacy technicians within the organization, allowing the redeployment of  
180 pharmacists' time to drug therapy management activities. The pharmacy executive works with  
181 state and federal regulatory agencies to support this expansion in the role of the pharmacy  
182 technician. He or she develops programs that fully leverage the use of students and residents  
183 within the organization, which includes participating in the development of student and  
184 resident standards to ensure that education and training reflects the needs of patients and  
185 health systems, and to further expand the capability of the pharmacy enterprise. The pharmacy  
186 executive ensures effective and timely staff recruitment, orientation, training, education,  
187 mentoring, career development, performance review, and retention efforts.

188 **Regulatory and Accreditation Compliance.** The pharmacy executive ensures continued  
189 compliance with all national, state, and local regulations related to medications and their  
190 management. He or she is responsible for the implementation of Board of Pharmacy, Drug  
191 Enforcement Agency, Centers for Medicare and Medicare Services, The Joint Commission and  
192 other medication management accreditation standards; for maintaining ASHP accreditation,  
193 where applicable (e.g., residency and technician training); and for the implementation of best  
194 practices. When applicable, the pharmacy executive is responsible for compliance oversight of  
195 the 340B program for the covered entity, all covered outpatient departments and contract  
196 pharmacy arrangements.

197 **Research and Educational Missions.** The pharmacy executive has an integral role in supporting  
198 the organization's research and educational missions by overseeing investigational drug  
199 services, fostering staff and resident research, participation in organizational grant funding  
200 applications and managing student and residency educational programs.

201 **Institutional Representation and Leadership.** The pharmacy executive demonstrates the  
202 personal leadership qualities and business acumen essential to operate effectively within the  
203 health system and to advance the profession and practice of pharmacy. He or she serves as the  
204 primary pharmacy representative on relevant committees of the organization's leaders to  
205 ensure that medication management systems and pharmaceutical services meet the needs of  
206 patients and health care providers across the continuum of care. The pharmacy executive  
207 assumes a leadership role within the profession through active participation in local, state, and  
208 national professional associations.

## Conclusion

209 Complex hospital and health systems should have a pharmacy executive responsible for the

210 strategic planning, design, operation, and improvement of the organization's medication  
211 management system. This individual must be properly positioned within the organization to  
212 ensure the best utilization of his or her expertise in all decisions regarding medication  
213 management.

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pharmacists advancing healthcare

# House of Delegates

## Board of Directors Report on the Council on Pharmacy Practice (Final)

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

Steve Rough, Board Liaison

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## Policy Recommendations

### 1

### Support for the Second Victim of Medical Errors

- 1 To acknowledge that healthcare personnel may become second victims of medical
- 2 errors; further,
- 3 To recognize that a just culture environment must include a support system for second
- 4 victims; further,
- 5 To encourage healthcare organizations to establish programs to support second
- 6 victims; further,
- 7 To educate healthcare professionals about the second-victim effect and available
- 8 resources.

#### **Rationale**

The [University of Missouri Health System](#) has defined second victims as “healthcare providers who are involved in an unanticipated adverse patient event, in a medical error and/or a patient-related injury and become victimized in the sense that the provider is traumatized by the event.” Frequently, these individuals feel personally responsible for the patient outcome. Many feel as though they have failed the patient, second-guessing their clinical skills and knowledge base. Individuals involved in a serious adverse patient event may experience the symptoms of post-traumatic stress disorder and may require support to successfully manage the experience.

Healthcare organizations have emphasized establishing a just culture environment to encourage individuals to speak up when they are aware of medication errors. Studies have indicated that many second victims did not feel they received organizational support after these events, however. The Joint Commission, the [Institute for Healthcare Improvement](#), the [Institute for Safe Medication Practices](#) (ISMP), and others have advocated for support systems for second victims. The Joint Commission Leadership Standards state that leaders will “make support systems available for staff that have been involved in an adverse or sentinel event.”

Healthcare organizations will have to tailor these support system to their needs. Such support systems may, for example, be tiered, with the first tier being unit or department support; the second tier, trained peer support, including patient-safety and risk-management staff; and the third tier, professional counseling support, such as employee assistance programs or social workers. Education of staff on resources available to support the second victim is critical to avoiding adverse impact on the second victim.

**Background**

The Council considered the available literature on supporting second victims. The Council noted cases in which employment is reassigned or terminated, or the individual leaves their profession because of concern for the future, or in extreme cases commits suicide. Overall, approximately two-thirds of the individuals involved as second victims feel they did not receive support from their organization. The Council noted examples of programs developed by healthcare organizations to support second victims, and the significant amount of literature addressing this issue. Organizations that have responded to this issue have developed organization-wide policies, and a program of responses depending on the incident and the individual. The Council noted that this is an issue for a variety of pharmacy staff, including pharmacists, pharmacy technicians, and other support staff. The Council also noted that it is applicable to both medication errors and medical errors.

The Council reviewed ASHP policies 1115, [Just Culture](#), and 1021, [Just Culture and Reporting Medication Errors](#), and concluded that new policy is needed because those policies address creating a just culture but do not address the second victim.

**2****Standardization of Doses**

- 1 To recognize that standardization of medication doses within healthcare organizations
- 2 reduces medication errors and improves information technology interoperability,
- 3 operational efficiency, and transitions of care; further,
  
- 4 To encourage healthcare organizations to develop standardized doses specific to their
- 5 patient populations; further,
  
- 6 To promote publication and education about best practices in standardizing medication
- 7 doses.

**Rationale**

Standardization and simplification are widely accepted methods for reducing variability in processes with risk for error. Standardization of medication doses reduces waste and improves efficiency. Computer databases can be built with standard dosage forms, facilitating information technology interoperability. Simplified instruction of patients and caregivers improves administration in the home and patient adherence.

The standardization of liquid doses has been successfully accomplished in hospitals. Standardization of doses is also applicable to parenteral nutrition solutions and other injectable dosage forms. Standardization of doses within a hospital or health system would reduce waste and the potential for errors in those settings. The strict application of pediatric weight-based dosing, for example, leads to a large number of different doses being used, and many of those

doses must then be prepackaged dose-by-dose due to limited stability of liquid and injectable dosage forms.

Additional studies to determine best practices for standardization of medication doses and education of healthcare practitioners are needed to facilitate broad adoption of this practice.

### **Background**

In 2013, the House of Delegates approved ASHP policy 1306, [Standardization of Intravenous Drug Concentrations](#), and in 2014 the House approved ASHP policy 1401, [Standardization of Oral Liquid Medication Concentrations](#), both of which addressed standardization at a national level. Approval of both policies was primarily based on improvement in patient safety, but efficiencies in dispensing and reducing waste are also achievable with standardized doses. The Council observed that excellent examples of standardization of concentrations have been published but noted that there are fewer published examples of standardization of doses.

The Council discussed several opportunities that exist related to standardization of doses. Standardization of doses has been successful in preparation of total parenteral nutrition, pediatric settings, intravenous solutions, and oral liquids. In addition, some healthcare systems have standardized medications with low side effect profiles or wide therapeutic windows. Additional formulations that may be considered for standardization of doses include:

- Medications used in high-risk populations (e.g., pediatric patients);
- Widely used medications (e.g., enoxaparin); and
- Specific high-cost medications.

The Council concluded that the focus of this policy should be at the organizational (hospital and health-system) level until the evidence for this practice is better established. The Council believed that promulgation of this policy would serve to encourage adoption of the practice, enhancing patient safety, as well as leading to publication of evidence for specific dosage practices that would facilitate standardization.

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

## 3

### Prescription Drug Abuse

- 1 To affirm that pharmacists have leadership roles in recognition, prevention, and
- 2 treatment of prescription drug abuse; further,
- 3 To promote education on prescription drug abuse, misuse, and diversion-prevention
- 4 strategies.

**Rationale**

Abuse of prescription opioid pain relievers caused more than 16,600 overdose deaths in 2010, a fourfold increase over 2000. Prescription drug abuse has also been linked to increased use of heroin; four of five recent heroin initiates had previously used prescription pain relievers nonmedically.

Pharmacy has been active in efforts to combat prescription drug abuse. ASHP and other pharmacy organizations [testified to the Senate Health, Education, Labor, and Pensions Committee](#) on strategies to address prescription drug abuse, including enhancing state prescription drug monitoring programs, making naloxone more available, and public education. As medication-use experts and accessible healthcare providers, pharmacists have a frontline, leadership role in curbing prescription drug abuse. Education of pharmacists, other healthcare professionals, and the public are critically important to these efforts.

**Background**

The Council considered this topic in response to a recommendation from the House of Delegates. The Council reviewed evidence about potential roles for pharmacists, including an article in the September 15, 2014, edition of the *American Journal of Health-System Pharmacy (AJHP)*, “The opioid abuse and misuse epidemic: Implications for pharmacists in hospitals and health systems.” The Council noted that ASHP members and staff are already engaged nationally and on the state and local levels. Given the scope of this major public health issue, however, a sustained, multi-faceted effort will be needed, and the Council concluded that a broad statement of ASHP policy regarding the pharmacist’s role in combating prescription drug abuse is needed.

**4****Pharmacist’s Role in Urgent and Emergency Situations**

- 1 To affirm that pharmacists should participate in planning and providing emergency
- 2 treatment team services; further,
  
- 3 To advocate that pharmacists participate in decision-making about the contents of code
- 4 carts, emergency medication kits and trays, and the role of pharmacists in medical
- 5 emergencies; further,
  
- 6 To advocate that pharmacists serve on cardiopulmonary resuscitation and rapid
- 7 response teams, and that those pharmacists receive appropriate training and maintain
- 8 appropriate certifications.

**Rationale**

Pharmacists have a leadership role in many hospitals in planning for emergency treatment team services. ASHP National Survey data show that approximately 40% of hospitals have pharmacist participation in cardiopulmonary resuscitation (CPR) teams. This role includes developing policy on the contents of code carts and other supplies as well as establishing the

role of the pharmacist in supporting these services. The literature demonstrates that pharmacists can make significant contributions to CPR and other emergency response teams as medication-use leaders and as participants, and there is evidence that better patient outcomes result when pharmacists participate. Pharmacists participating in this role should receive appropriate training and certification (e.g., Basic Life Support, Advanced Cardiopulmonary Life support, and Pediatric Acute Life Support).

### **Background**

The Council considered this topic in response to a recommendation from an ASHP member. The [ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals](#) address pharmacist participation in medical emergencies, and ASHP encouraged participation in its 2010 Pharmacy Practice Model Initiative (PPMI) Hospital Self-Assessment questionnaire (question 39, Do pharmacists participate on your hospital's rapid response team? and question 40, Do pharmacists participate on your hospital's cardiopulmonary resuscitation teams?). Given the ASHP National Survey data indicating less than 50% adoption of this practice, however, the Council concluded that a sharply focused policy on the topic would help raise awareness and promote advocacy.

The Council agreed that pharmacists should be actively involved in any urgent or emergency situation in which medications are used. The Council noted that support currently exists for pharmacists on rapid response and cardiopulmonary response teams in a variety of healthcare organizations, including in ambulatory care settings. The Council recognized that response is often difficult, that the limited number of pharmacists at some facilities may lead to situations in which pharmacists are responding only when available, and that it may not be possible to respond to all situations when there is not continuous (24-hours-per-day, seven days-per-week) coverage. However, Council recognized that pharmacists should play a leadership role in developing processes that support safe and effective medication use for urgent and emergency situations.

## 5

### **Excipients in Drug Products**

- 1 To advocate that manufacturers remove unnecessary, potentially allergenic excipients
- 2 from all drug products; further,
  
- 3 To advocate that manufacturers declare the name and derivative source of all
- 4 excipients in drug products on the official label; further,
  
- 5 To advocate that vendors of medication-related databases incorporate information
- 6 about excipients; further,
  
- 7 To foster education on the allergenicity of excipients and documentation in the patient
- 8 medical record of allergic reactions to excipients.

(Note: This policy would supersede ASHP policy 0808.)

**Rationale**

Excipients are intended to be inactive ingredients that assist in delivering a pharmaceutically elegant medication. In some patients, however, excipients cause allergic responses or aggravate medical conditions. Examples include patients with celiac disease reacting to gluten in a drug product or pediatric patients with a red-dye allergy reacting to a suspension containing red dye. Inclusion of excipients in drug product labeling, including their derivative source (the botanical, animal, or other source from which the excipient is originally derived), would allow substitution of nonallergenic alternative, but in many cases patients may not be aware of the allergy or it may not be documented in the patient medical record. Manufacturers are therefore encouraged to avoid putting allergenic excipients (e.g., red or yellow dye, gluten) in drug products when possible.

Education of manufacturers, pharmacists and other healthcare professionals, and patients regarding the allergenicity of excipients will be required. Medication-related databases will need to be configured to include information about drug product excipients, and electronic health record systems will need to permit documentation of allergies and medical conditions related to excipients.

**Background**

The Council considered this topic in response to a recommendation from the House of Delegates. The Council noted that there are a large number of allergenic excipients in drug products, and that allergic patients requiring those drugs will need to have the drug preparation compounded for them. In addition, the Council noted that nomenclature for excipients is not standardized. The Council discussed the distinction between intolerance and documented allergies to excipients and noted the challenge in differentiating between and responding to the two. The Council also noted that the removal of excipients may result in problematic changes in bioavailability and therapeutic action. The Council discussed promotion of the pharmacist's role in identifying the most appropriate product based on allergies and potential patient adverse drug reactions. The Council discussed the need for additional pharmacist education on allergenic excipients.

The Council recommended amending ASHP policy 0808 as follows (underline indicates new text):

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

~~(Note: *Derivative source* means the botanical, animal, or other source from which the excipient is originally derived.)~~

The current policy advocates disclosure of excipients, which can assist with identifying situations in which a nonallergenic alternative (e.g., a pharmacy compounded product) may be substituted. The Council supported broadening the policy to advocate that allergenic excipients not be added to drug products when possible, that information about excipients be included in medication-related databases, and that allergic reactions to excipients be included in the patient medical record. The definition of *derivative source* was moved to the policy's rationale.

## 6

### Online Pharmacy and Internet Prescribing

- 1 To support efforts to regulate prescribing and dispensing of medications via the
- 2 Internet; further,
  
- 3 To support legislation or regulation that requires online pharmacies to list the states in
- 4 which the pharmacy and pharmacists are licensed, and, if prescribing services are
- 5 offered, requires that the sites (1) ensure that a legitimate patient-prescriber
- 6 relationship exists (consistent with professional practice standards) and (2) list the
- 7 states in which the prescribers are licensed; further,
  
- 8 To support mandatory accreditation of online pharmacies by the National Association
- 9 of Boards of Pharmacy Verified Internet Pharmacy Practice Sites or Veterinary-Verified
- 10 Internet Pharmacy Practice Sites; further,
  
- 11 To support appropriate consumer education about the risks and benefits of using online
- 12 pharmacies; further,
  
- 13 To support the principle that any medication distribution or drug therapy management
- 14 system must provide timely access to, and interaction with, appropriate professional
- 15 pharmacist patient-care services.

(Note: This policy would supersede ASHP policy 0523.)

#### **Rationale**

ASHP's vision to make medication use safe, optimal, and effective includes supporting efforts to protect the public from unscrupulous website operators who illegally provide medications online. Patients are entitled to know whether the healthcare providers prescribing and dispensing their medications are licensed, and in which states they are licensed. ASHP supports legislation and regulations that would require online pharmacies to provide such information. To further guarantee patient safety, ASHP advocates mandatory accreditation of such sites by the National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) and Veterinary-Verified Internet Pharmacy Practice Sites (Vet-VIPPS) accreditation

programs for online pharmacies to assure the public that the pharmacies are compliant with federal and state regulations and NABP criteria. Education of consumers will be required to ensure that online pharmacies are used wisely, and use of online pharmacies should involve appropriate pharmacist counseling.

### **Background**

As part of sunset review, the Council recommended that ASHP policy 0523 be amended as follows (underline indicates new text; ~~strikethrough~~ indicates deleted text):

To support ~~collaborative efforts of the Food and Drug Administration, the National Association of Boards of Pharmacy (NABP), and the Federation of State Medical Boards, as stated in the Principles of Understanding on the Sale of Drugs on the Internet,~~ to regulate prescribing and dispensing of medications via the Internet; further,

To support legislation or regulation that requires online pharmacies ~~World Wide Web sites~~ to list the states in which the pharmacy and pharmacists are licensed, and, if prescribing services are offered, requires that the sites (1) ensure that a legitimate patient-prescriber relationship exists (consistent with professional practice standards) and (2) list the states in which the prescribers are licensed; further,

To support mandatory accreditation of online pharmacies by the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites or Veterinary-Verified Internet Pharmacy Practice Sites ~~of pharmacy Web sites and appropriate consumer education about the risks and benefits of using Internet pharmacies;~~ further,

To support appropriate consumer education about the risks and benefits of using online pharmacies; further,

To support the principle that any medication distribution or drug therapy management system must provide timely access to, and interaction with, appropriate professional pharmacist patient-care services.

## 7

## Standardization of Small-Bore Connectors To Avoid Wrong-Route Errors

- 1 To advocate for use of medication administration device connectors and fittings that
- 2 are designed to prevent misconnections and wrong-route errors; further,
- 3 To encourage healthcare organizations to prepare for safe transition to use of
- 4 medication delivery device connectors and adapters that meet International
- 5 Organization for Standardization standards; further,
- 6 To oppose the use of syringes with Luer fittings for other than intravascular or
- 7 hypodermic routes of administration; further,
- 8 To identify and promote the implementation of best practices for preventing wrong-
- 9 route errors.

(Note: This policy would supersede ASHP policy 1018.)

### **Rationale**

Interconnectivity among drug delivery devices and their fittings is a significant and preventable cause of serious or fatal wrong-route errors. Connector and tubing design unique to the route of administration that cannot be linked to a device used for a different route is the strongest type of control for these errors.

An international joint working group composed of the [International Organization for Standardization \(ISO\)](#), [Association for the Advancement of Medical Instrumentation \(AAMI\)](#), FDA, manufacturers, clinicians, and other regulators recently initiated development of [new ISO connector standards](#) for medical devices for intravascular/hypodermic, limb cuff, enteral, neuraxial, and breathing systems/pressurized medical gas applications. Urethral standards are also planned, but not yet initiated. The new ISO standards are voluntary and intended to facilitate global standardization of medical devices. The FDA has announced that it will only approve or clear an enteral device with a new small-bore connector if it meets the ISO standard or equivalent alternative method. (Small-bore [less than 8.5 mm diameter] connectors are used to link or join devices, accessories, and components for intravascular/hypodermic, neuraxial [epidural, intrathecal, spinal], urinary, enteral, and breathing system/medical gas delivery of medications.) Subsequently, the first ISO standard for enteral device connectors ([ANSI/AAMI/ISO 80369-1](#)) has been adopted industrywide. New connectors will be phased in, beginning fourth quarter 2014. The Joint Commission recently published Sentinel Event Alert #53, [Managing risk and transition during transition to new ISO tubing connector standards](#). The alert provides suggested actions from the 2014 *Get Connected* campaign provided by the Global Enteral Device Supplier Association (GEDSA), as well as updates to the recommendations from the 2006 Sentinel Event Alert #36 on tubing misconnections.

In addition, the following statements were issued from the 2008 Global Conference on the Future of Hospital Pharmacy in Basel, Switzerland:

Pharmacists should ensure that strategies and policies are implemented to prevent wrong route errors, including, for example, labeling of intravenous tubing near insertion site to prevent misconnections, and use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines.

Oral syringes that are distinctly different from hypodermic syringes should be used to prevent injection of enteral or oral medicines, especially in pediatric patients.

### **Background**

As part of sunset review, the Council recommended that ASHP policy 1018 be amended as follows (underline indicates new text, ~~strike through~~ indicates deletions):

To advocate for ~~development and~~ use of medication administration device connectors and fittings that are designed to prevent misconnections and wrong-route errors; further,

~~To support the use of oral syringes that are readily distinguishable from injectable syringes and connect only to oral or enteral adapters and fittings; further,~~

To encourage healthcare organizations to prepare for safe transition to use of medication delivery device connectors and adapters that meet International Organization for Standardization standards; further,

To oppose the use of ~~injectable~~ syringes with Luer fittings for other than ~~injectable~~ intravascular or hypodermic routes of administration; further,

To identify and promote the implementation of best practices for preventing wrong-route errors.

## 8

## Medication Safety Officers Role

To discontinue ASHP policy 1019, which reads:

- 1 To advocate that accountability for development and maintenance of a medication
- 2 safety program in hospitals and health systems be assigned to a qualified individual
- 3 (i.e., a medication safety officer or leader of a medication safety team); further,
  
- 4 To advocate that individuals in these roles have the authority and autonomy to
- 5 establish priorities for medication-use safety and make the necessary changes as
- 6 authorized by the medical staff committee responsible for medication-use policy;
- 7 further,
  
- 8 To affirm that pharmacists are uniquely prepared by education, experience, and
- 9 knowledge to assume the role of medication safety officer or other leadership role in all
- 10 activities that ensure the safety, effectiveness, and efficiency of the medication-use
- 11 process; further,
  
- 12 To support all pharmacists in their leadership roles in organizational medication-use
- 13 safety, reflecting their authority over and accountability for the performance of the
- 14 medication-use process.

### **Background**

The Council recommended discontinuing this policy because it is redundant with the [ASHP Statement on the Role of the Medication Safety Leader](#), which was approved in 2013. The statement provides a more contemporary discussion of the considerations of developing a medication safety leader role.

## 9

## Pharmacist Participation in Capital Punishment

- 1 To acknowledge that an individual's opinion about capital punishment is a personal
- 2 moral decision; further,
  
- 3 To oppose pharmacist participation in capital punishment; further,
  
- 4 To reaffirm that pharmacists have a right to decline to participate in capital punishment
- 5 without retribution.

(Note: This policy would supersede ASHP policy 8410.)

**Rationale**

Since 1977, when Oklahoma became the first state to adopt execution by lethal injection, many healthcare professional organizations have adopted policies opposing participation by members of their respective professions in capital punishment. The American Medical Association (AMA), the American Nurses Association (ANA), and the American Pharmacists Association (APhA) are among these groups; however, a wide variety of organizations have spoken out on the issue. The consistent theme of the opposition of those organizations is that the intentional infliction of death is contrary to the mission of healthcare and therefore unethical. ASHP's previous policy on pharmacist participation in capital punishment, which was adopted in 1984 and has been reaffirmed several times since, emphasized the pharmacist right to conscience when deciding whether to participate in capital punishment.

The role of pharmacists in execution by lethal injection changed substantially after Hospira relocated its thiopental sodium manufacturing to Italy in 2011. The European Union bans the export of thiopental sodium to countries where it may be used in executions, including the U.S. The ban resulted in severe shortages of the drug, which was the cornerstone of the three-drug cocktail used in lethal injections. (At least nine drug manufacturers have followed suit in prohibiting use of their products for lethal injection.) States responded by substituting compounded anesthetic preparations or instituting other drug protocols, which came under criticism after several executions in which prisoners appeared to suffer despite being medicated. These developments increased the role of pharmacists in preparing and/or compounding drugs for execution by lethal injection, which in turn increased the scrutiny of that role both inside and outside the profession.

That increased scrutiny comes at a time when pharmacists are rapidly expanding their roles on the patient care team and are being recognized as patient care providers. This proposed policy developed by the ASHP Council on Pharmacy Practice recognizes that one's beliefs about capital punishment are a personal, individual decision but opposes pharmacist participation in capital punishment because it is contrary to their role as healthcare providers. Given the ethical questions about pharmacist participation in capital punishment, pharmacists should not be punished for their refusal to participate.

**Background**

The Council recommended revising ASHP policy 8410, Use of Drugs in Capital Punishment, which reads:

To support the following concepts:

- The decision by a pharmacist to participate in the use of drugs in capital punishment is one of individual conscience.
- Pharmacists, regardless of who employs them, should not be put at risk of any disciplinary action, including loss of their jobs, because of refusal to participate in capital punishment.

The Council reviewed the positions of several organizations of healthcare professionals in crafting the revised policy position. As in the Council's revised language, the AMA recognizes that "[a]n individual's opinion on capital punishment is the personal moral decision of the individual." The AMA policy goes on to state that "A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a

legally authorized execution” and goes on to define what constitutes “participation” in an execution. The Council declined to specify what would constitute pharmacist participation in capital punishment.

The ANA statement of position -- that they are “strongly opposed to nurse participation in capital punishment” -- provides this concise justification: “Participation in executions, either directly or indirectly, is viewed as contrary to the fundamental goals and ethical traditions of the nursing profession.” The Council’s revised language strongly echoes ANA’s statement.

APhA’s has three policy planks on pharmacist involvement in execution by lethal injection:

1. APhA opposes the use of the term “drug” for chemicals when used in lethal injections.
2. APhA opposes laws and regulations which mandate or prohibit the participation of pharmacists in the process of execution by lethal injection.
3. The American Pharmacists Association discourages pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care.

The Council’s revised language echoes the third plank, but the Council declined to include concepts similar to the first two in its revised language.

The Council also reviewed the policy of the International Academy of Compounding Pharmacists (IACP), which “discourages its members from participating in the preparation, dispensing, or distribution of compounded medications for use in legally authorized executions,” in its deliberation. The Council also noted that a number of healthcare organizations (e.g., American Psychiatric Association, American Society of Anesthesiologists, American Public Health Association, American Correctional Health Services Association, World Medical Association, National Commission on Correctional Health Care , and International Council of Nurses) have policies against participation by members in capital punishment.

**10**

## **ASHP Statement on the Pharmacist’s Role in Substance Abuse, Prevention, Education and Assistance**

- <sup>1</sup> To approve the ASHP Statement on the Pharmacist’s Role in Substance Abuse
- <sup>2</sup> Prevention, Education, and Assistance. ([Appendix](#))

### **Background**

The ASHP statement was updated to address changes in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) as well as incorporate more recent statistics on drug abuse, including prescription drug abuse.

## Board Actions

### Sunset Review of Professional Policies

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

- [Pharmacist’s Right of Conscience and Patient’s Right of Access to Therapy](#) (0610)
- [Standardization of Medication Formulary Systems](#) (9601)
- [Human Factors Concepts](#) (9609)
- [Drug Shortages](#) (0002)
- [Drug Names, Labeling, and Packaging Associated with Medication Errors](#) (0020)
- [Medication Errors and Risk Management](#) (0021)
- [Mandatory Labeling of the Presence of Latex](#) (0501)
- [Health Care Quality Standards and Pharmacy Services](#) (0502)
- [Electronic Information Systems](#) (0507)
- [Mandatory Tablet Splitting for Cost Containment](#) (0525)
- [Role of Pharmacists in Safe Technology Implementation](#) (1020)
- [Just Culture and Reporting Medication Errors](#) (1021)
- [Patient Access to Pharmacy Services in Small and Rural Hospitals](#) (1022)
- [Scope and Hours of Pharmacy Services](#) (1023)
- [Use of Two Patient Identifiers in the Outpatient Setting](#) (1024)
- [ASHP Statement on the Use of Dietary Supplements](#)

## Other Council Activity

### ASHP Guidelines on the Pharmacist’s Role in the Development, Implementation, and Assessment of Critical Pathways

The Council voted to revise the [ASHP Guidelines on the Pharmacist’s Role in the Development, Implementation and Assessment of Critical Pathways](#). As part of sunset review the Council reviewed these guidelines and determined that the document, originally approved in 2004, is no longer current because it does not address the use of the electronic medical record, a key strategy for implementing pathways, and its terminology is not current. The Council agreed that the topic needs to be addressed in ASHP guidelines because it is important to quality of care and clinical practice.

### Pharmacist Role with Compassionate-Use Medications

The Council discussed compassionate use of medications and current “right-to-try” initiatives in response to a recommendation by ASHP staff. The Council developed the following language for a policy recommendation:

- To support patient access to compassionate use medications when criteria for use are met; further,
- To advocate that pharmacists be recognized as essential members of the healthcare teams related to compassionate-use medications and provide leadership on their use.

After discussion with the Council on Public Policy it was agreed that those concepts will be incorporated into the Council on Public Policy recommendation on the topic.

The Council considered ASHP staff reports of discussions with members, articles about recent “right-to-try” legislation, information about the role of the FDA and the role of the study sponsor in allocating medication for the compassionate-use patient, and current ASHP policy (the [Code of Ethics for Pharmacists](#) and policy 0610, [Pharmacists Right of Conscience and Patient’s Right of Access to Therapy](#)). The Council also considered the role of the pharmacist as a member of the healthcare team and as medication-use leader in the healthcare system. Compassionate use of medications is approved by the FDA on a case-by-case basis under its [Expanded Access Program](#).

## USP General Chapter 800: Hazardous Drugs – Handling in Healthcare Settings

United States Pharmacopoeia (USP) General Chapter 800: [Hazardous Drugs – Handling in Healthcare Settings](#) was made available for comment by USP earlier in 2014. According to USP the purpose of the new proposed general chapter is to provide standards to protect personnel and the environment when handling hazardous drugs. The new proposed general chapter defines processes intended to provide containment of hazardous drugs to as low a limit as reasonably achievable.

Council members suggested that the most significant proposed provisions in the new chapter relate to construction of facilities specifically for HD storage and preparation with negative air pressure and external exhaust. Particularly for low-volume hospitals and clinics this requirement may be a significant financial and operational challenge. While ASHP expressed support of the intent of the new chapter, to protect healthcare workers from exposure to hazardous substances, ASHP recommended a two-year delay before the chapter becomes official to allow healthcare organizations sufficient time for planning and budgeting activities.

Council members identified the following steps that ASHP should consider:

1. Reevaluate current ASHP Guidelines on Handling Hazardous Drugs published in 2006 when the USP general chapter is finalized.
2. Update the ASHP guidelines.
3. Develop a hospital/health-system tool kit: gap analysis, risk assessment for evaluating risk of individual drugs, and model medical surveillance program.
4. Develop a guidance document for construction engineers.

## Ambulatory Care Conference and Summit Consensus Recommendations

The Council reviewed 10 recommendations from the Ambulatory Care Conference and Summit held in March 2014. It was noted that each Council was reviewing select recommendations most closely aligned with the Council's area of responsibility. The intent of the review was to consider the alignment of the recommendations with current policy. The Council reviewed a matrix identifying current policies, statements, and guidelines that most closely align with the recommendation and identified policy and educational needs. (It was noted that the Summit recommendations are aspirational and that policies, standards, and guidelines may not align with the recommendations based on this different focus.) The Council recommended that a similar overall matrix listing all 25 recommendations be developed and reviewed. Melanie Dodd, Chair of the Section of Ambulatory Care Practitioners, indicated that this matrix development and review is already in process.

## Prescription Drug Abuse

In addition to making a policy recommendation regarding prescription drug abuse, the Council recognized that there are statements and initiatives that have been developed by different groups that ASHP may want to endorse or actively support (e.g., [The National Drug Control Strategy](#)). The Council will search for key guidance documents that they can review and consider recommending for endorsement.

## Report on Previous Council Recommendations

The Council reviewed the Report on Implementation of 2013 ASHP House of Delegates Actions and Recommendations. Status reports for the following items were reviewed:

- Policy 1305: Education About Performance-Enhancing Substances
- Policy 1306: Standardization of Intravenous Drug Concentrations
- Policy 1318: ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance

## Review of Documents in Development

The Council reviewed the current schedule for development of guidance documents recommended by the Council. There was a reaffirmation of need for the documents slated for development, and several Council members volunteered to assist in guidelines development. Conference calls will be arranged to coordinate progress on the priority items that were identified.

## Appendix

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

#### Position

1 The American Society of Health-System Pharmacists (ASHP) believes that pharmacists have the  
2 unique knowledge, skills, and responsibilities for assuming an important role in substance  
3 abuse prevention, education, and assistance. Pharmacists, as health care providers, should be  
4 actively involved in reducing the negative effects that substance abuse has on society, health  
5 systems, and the pharmacy profession. Further, ASHP supports efforts to rehabilitate  
6 pharmacists and other health-system employees whose mental or physical impairments are  
7 caused by substance abuse.

#### Background

8 The term “substance abuse,” is commonly used to describe the hazardous or addictive use of  
9 psychoactive substances with either addictive, typically depressing or stimulating, or perception  
10 distorting properties. The American Psychiatric Association’s *Diagnostic and Statistical Manual  
11 of Mental Disorders*, 5<sup>th</sup> edition (DSM-5) includes substance use disorders, typically considered  
12 addictions with severity categories, and substance-induced disorders, typically intoxication or  
13 withdrawal, in its “Substance-Related and Addictive Disorders” chapter.<sup>1</sup> Examples include  
14 alcohol, tobacco, “street” drugs (e.g., marijuana, lysergic acid diethylamide [LSD], phencyclidine  
15 [pcp], cocaine, methamphetamine, methylenedioxymethamphetamine [MDMA], inhalants,  
16 gammahydroxybutyrate [GHB], heroin, K2/Spice, salvia, bath salts), and the nonmedical use or  
17 the overuse of psychoactive and other prescription and nonprescription drugs (e.g.,  
18 hydrocodone, oxycodone, ketamine, methadone, dextromethorphan).

19 Substance abuse is a major societal problem. The 2012 National Household Survey on Drug  
20 Use and Health (NSDUH), a primary source of statistical information on drug abuse in the U.S.  
21 population, estimated that (a) 23.9 million Americans (or 9.2% of the population 12 years of age  
22 or older) had used an illicit drug\* in the past month, (b) 2.8 million Americans were classified  
23 with dependence or abuse of both illicit drugs and alcohol, (c) 4.5 million had dependence or  
24 abuse of illicit drugs but not alcohol, and (d) 14.9 million Americans were dependent on  
25 alcohol.<sup>2</sup> A 2001-2002 study conducted using DSM-IV criteria in the U.S. suggested of substance  
26 abuse/dependence disorders suggested a lifetime prevalence of alcohol use disorders of 30.3%,  
27 of drug use disorders of 10.3%, of alcohol dependence (alcoholism) of 12.5% (17.4% for men;  
28 8.0% for women)<sup>3</sup> and of other drug dependence (“drug addiction”), excluding tobacco, at 2.6%  
29 (3.3% for men; 2.0% for women).<sup>4</sup> Studies suggest that the prevalence of drug abuse among  
30 health professionals appears to be similar to that in the general population.<sup>5-7</sup> Given their  
31 access, however, health professionals abuse prescription drugs more often and “street” drugs  
32 less often than does the general population.

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\*The National Survey on Drug Use and Health obtains information on nine categories of illicit drug use: use of marijuana, cocaine, heroin, hallucinogens, and inhalants, as well as the nonmedical use of prescription-type pain relievers, tranquilizers, stimulants, and sedatives.

33 Substance abuse frequently coexists with and complicates other psychiatric disorders, and it  
34 is a common and often unrecognized cause of physical morbidity. Intravenous drug abuse is a  
35 major factor in the spread of human immunodeficiency virus (HIV) and hepatitis. Alcohol is a  
36 major factor in cirrhosis of the liver, and tobacco is a key contributor to emphysema and lung  
37 cancer. Collectively, substance abuse contributes significantly to morbidity and mortality in our  
38 population and to the cost of health care.

39 Substance abuse is also a serious workplace problem. The 2012 NSDUH reported that  
40 approximately 14.6 million Americans reporting past month illicit drug use were currently  
41 employed full- or part-time.<sup>2</sup> Substance abuse by employees of health care organizations leads  
42 to reduced productivity, increased absenteeism, drug diversion, and, almost certainly,  
43 increased accidents and medication misadventures. Consequently, it affects the quality of  
44 patient care, liability, and operational and health care costs.

45 The abuse, or non-medical use, of prescription medications has also become a prevalent  
46 issue. Nonmedical use of prescription drugs among youths aged 12 to 17 and young adults aged  
47 18 to 25 in 2012 was the second most prevalent illicit drug use category, with marijuana being  
48 first.<sup>2</sup> The survey also found that over half of all prescription drug abusers had obtained the  
49 prescription medication "from a friend or relative for free" as compared to the 3.9% who had  
50 obtained the medication from a drug dealer or other stranger.

51 Pharmacists have unique, comprehensive knowledge about the safe and effective use of  
52 medications and about the adverse effects of their inappropriate use. The provision of  
53 pharmaceutical care to individual patients involves pharmacists assessing the appropriateness  
54 of pharmacotherapy, counseling, and monitoring medication-use outcomes. Health-system  
55 pharmacists have responsibilities for ensuring a safe and effective medication-use system,  
56 including legal and organizational responsibilities for medication distribution and control across  
57 the continuum of practice settings within health care organizations. With this combination of  
58 knowledge and organizational responsibilities, pharmacists are prepared to serve in leadership  
59 and service roles in substance abuse prevention and education and assist in a variety of patient  
60 care, employee health, and community activities.

### **Responsibilities**

61 The scope of substance abuse responsibilities of pharmacists varies with the health care  
62 organization's mission, policies and procedures, patient population, and community. The  
63 responsibilities listed below should be adapted to meet local needs and circumstances. Each  
64 responsibility is intended to be applicable to any substance of abuse; therefore, specific  
65 substances are generally not mentioned. Pharmacists should be involved in substance abuse  
66 prevention, education, and assistance by performing the following activities:

#### ***Prevention***

- 67 1. Participating in or contributing to the development of substance abuse prevention and  
68 assistance programs within health care organizations. A comprehensive program should  
69 consist of (a) a written substance abuse policy; (b) an employee education and awareness  
70 program; (c) a supervisor training program; (d) an employee assistance program; (e) peer  
71 support systems, such as pharmacist recovery networks; and (f) drug testing.<sup>8</sup>

- 72 2. Participating in public substance abuse education and prevention programs (e.g., in primary  
73 and secondary schools, colleges, churches, and civic organizations) and stressing the  
74 potential adverse health consequences of the misuse of legal and use of illegal drugs.
- 75 3. Opposing the sale of alcohol and tobacco products by pharmacists and in pharmacies.
- 76 4. Establishing a multidisciplinary controlled-substance inventory system, in compliance with  
77 statutory and regulatory requirements, that discourages diversion and enhances  
78 accountability. Where helpful, for example, procedures might require the purchase of  
79 controlled substances in tamper-evident containers and maintenance of a perpetual  
80 inventory and ongoing surveillance system.
- 81 5. Working with local, state, and federal authorities in controlling substance abuse, including  
82 participation in state prescription drug monitoring programs, encouraging participation in  
83 appropriate prescription disposal programs, complying with controlled-substance reporting  
84 regulations, and cooperating in investigations that involve the misuse of controlled  
85 substances, especially diversion from a health care organization.
- 86 6. Working with medical laboratories to (a) identify substances of abuse by using drug and  
87 poison control information systems, (b) establish proper specimen collection procedures  
88 based on knowledge of the pharmacokinetic properties of abused substances, and (c) select  
89 proper laboratory tests to detect the suspected substances of abuse and to detect  
90 tampering with samples.
- 91 7. Discouraging prescribing practices that enable or foster drug abuse behavior (e.g.,  
92 prescribing a larger quantity of pain medication than is clinically needed for treatment of  
93 short-term pain).
- 94 8. Collaboration with outpatient and ambulatory care providers to prevent substance abuse  
95 after discharge.

### **Education**

- 96 1. Providing information and referral to support groups appropriate to the needs of people  
97 whose lives are affected by their own or another person's substance abuse or dependency.
- 98 2. Providing recommendations about the appropriate use of mood-altering substances to  
99 health care providers and the public, including those persons recovering from substance  
100 dependency and their caregivers.<sup>9</sup>
- 101 3. Fostering the development of undergraduate and graduate college of pharmacy curricula  
102 and pharmacy technician education on the topic of substance abuse prevention, education,  
103 and assistance.<sup>10</sup>
- 104 4. Providing substance abuse education to fellow pharmacists, other health care professionals,  
105 and other employees of their health care organization.
- 106 5. Instructing drug abuse counselors in drug treatment programs about the pharmacology of  
107 abused substances and medications used for detoxification.
- 108 6. Promoting and providing alcohol risk-reduction education and activities.
- 109 7. Maintaining professional competency in substance abuse prevention, education, and  
110 assistance through formal and informal continuing education.
- 111 8. Providing post-graduate training in addictions, pain management, and palliative care where  
112 feasible.
- 113 9. Conducting research on substance abuse and addiction.

- 114 10. Educating patients about the correct storage, handling, and proper disposal of prescription  
115 medications.

### **Assistance**

- 116 1. Assisting in the identification of patients, coworkers, and other individuals who may be  
117 having problems related to their substance abuse, and referring them to the appropriate  
118 people for evaluation and treatment.
- 119 2. Participating in multidisciplinary efforts to support and care for the health care  
120 organization's employees and patients who are recovering from substance dependency.
- 121 3. Supporting and encouraging the recovery of health professionals with alcoholism or other  
122 drug addictions. Major elements of an employer's support program might include (a) a  
123 willingness to hire or retain employees; (b) participating in monitoring and reporting  
124 requirements associated with recovery or disciplinary contracts; (c) maintaining an  
125 environment supportive of recovery; (d) establishing behavioral standards and norms among  
126 all employees that discourage the abuse of psychoactive substances, including alcohol; and  
127 (e) participating in peer assistance programs.
- 128 4. Collaborating with other health care providers in the development of the  
129 pharmacotherapeutic elements of drug detoxification protocols.
- 130 5. Providing pharmaceutical care to patients being treated for substance abuse and  
131 dependency.
- 132 6. Maintaining knowledge of professional support groups (e.g., state- and national-level  
133 pharmacist recovery networks) and other local, state, and national organizations, programs,  
134 and resources available for preventing and treating substance abuse (see "Other  
135 Resources").
- 136 7. Refusing to allow any student or employee, including health professionals, to work, practice,  
137 or be on-site for rotations within the health care organization while his or her ability to  
138 safely perform his or her responsibilities is impaired by drugs, including alcohol. The refusal  
139 should follow the organization's policies and procedures, the principles of ethical and  
140 responsible pharmacy practice, and statutory requirements. Practice should not be  
141 precluded after appropriate treatment and monitoring, if approved by the treatment  
142 provider or contract monitor (or both, when applicable).

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#### Other Resources

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24. Center for Substance Abuse Prevention (CSAP) Workplace Helpline (for employers). Telephone, 800- 967-5752; e-mail, [dwp@samhsa.hhs.gov](mailto:dwp@samhsa.hhs.gov).
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26. Community organizations are available to help with drug or alcohol problems. Treatment counselors may be valuable in developing assistance policies and in providing professional education about treatment and referral systems. Community drug abuse prevention organizations may be helpful in prevention efforts, including community drug education. Check your local telephone directory under headings such as Alcoholism Information and Treatment, Drug Abuse Information and Treatment, and Counselors.
27. Twelve-step groups (usually available locally unless otherwise noted; listed telephone numbers and Websites are for national headquarters):
  - a. Adult Children of Alcoholics (ACA); for adults who, as children, lived with alcoholic parents. Telephone, 562-595-7831; Website, [www.adultchildren.org](http://www.adultchildren.org).

- b. Al-Anon; provides information on alcoholism and alcohol abuse and refers callers to local Al-Anon support groups established to help people affected by others' alcohol misuse. Telephone, 757-563-1500; Website, [www.al-anon.org](http://www.al-anon.org).
  - c. Alateen; for adolescents affected by alcoholics. Website, [www.al-anon.alateen.org/for-alateen](http://www.al-anon.alateen.org/for-alateen).
  - d. Alcoholics Anonymous (AA); provides information and support to recovering alcoholics. Telephone, 212-870-3400; Website, [www.alcoholicsanonymous.org](http://www.alcoholicsanonymous.org).
  - e. Cocaine Anonymous (CA); for individuals with cocaine dependencies. Telephone, 310-559-5833; Website, [www.ca.org](http://www.ca.org).
  - f. International Doctors in Alcoholics Anonymous (IDAA) includes pharmacists in recovery regardless of degree (a national group that has an annual conference and recovery resources for doctoral degree health professionals.) Website is [www.idaa.org](http://www.idaa.org). IDAA Executive Director contact is [executive@idaa.org](mailto:executive@idaa.org).
  - g. Nar-Anon; for helping people affected by another's drug misuse. Telephone, 800-477-6291; e-mail [wso@nar.anon.org](mailto:wso@nar.anon.org).
  - h. Narcotics Anonymous (NA); provides information and support to recovering substance abusers. Telephone, 818-773-9999; Website, [www.na.org](http://www.na.org).
28. Advocacy and professional substance abuse education:
- a. Pharmacist Recovery Networks (PRNs) exist in most states in the U.S. to assist pharmacists (and often also pharmacy technicians and sometimes pharmacy students) with addictions or in addiction recovery. The [www.usaprn.org](http://www.usaprn.org) website includes information about these programs by state as well as information about other recovery-related resources.
  - b. The Pharmacy Section (cosponsored by APhA and APhA Academy of Students of Pharmacy) of the University of Utah School on Alcoholism and Other Drug Dependencies was a one-week seminar held each summer until 2014 (options are being considered to establish the School at another site beginning in 2015) for learning to deal with substance abuse problems as they affect the profession. Consult [www.usaprn.org](http://www.usaprn.org) for updates and current status of the School.



pharmacists advancing healthcare

# House of Delegates

## ASHP Statement on the Pharmacist's Role in Clinical Informatics

### Position

1 ASHP believes that pharmacists have the training, knowledge, background, and responsibility to  
2 assume a significant role in clinical informatics.

### Background

3 Healthcare organizations continue to invest a significant amount of financial and human  
4 resource in health information technology (HIT) initiatives, including advanced clinical systems,  
5 electronic health records, business intelligence and analytics tools, and applications that deliver  
6 the highest levels of patient safety and value. This growth has led to a considerable demand for  
7 HIT workers but more importantly has identified the need for a workforce with training and  
8 skills to create a successful and safe interface between HIT and the healthcare delivery system.  
9 This workforce must understand healthcare; information and communication technology; and  
10 the people, processes, and culture of an organization. The intersection of these skills has  
11 commonly been described as the discipline of biomedical and health informatics, more recently  
12 termed clinical informatics.<sup>1</sup> Evidence continues to emerge regarding the value a well-trained  
13 individual in clinical informatics can bring to an organization faced with implementing highly  
14 complex and transformative HIT systems.<sup>2, 3</sup>

15 Pharmacy informatics has grown to be an integral discipline within the clinical  
16 informatics domain, centered on the effective management and delivery of medication-related  
17 data, information, and knowledge across systems that support the medication-use process.  
18 Pharmacists' professional identity, education, training, and experience with medication  
19 management make them ideal candidates to play a significant role and fill a critical need in  
20 pharmacy informatics. Their firm understanding of core pharmacy operations, clinical practice,  
21 the medication-use process, standards, and regulations and their long history of utilizing



22 technology to support medication management provide the essential components for  
23 effectively transitioning into this role. Despite the growing number of formally trained  
24 pharmacy informaticists, the path and skills required for a career in informatics has varied  
25 considerably, emphasizing the need to build core competencies and grow the number of  
26 available programs.<sup>4-6</sup> The American Board of Medical Specialties (ABMS) recognition of clinical  
27 informatics as a physician subspecialty will likely play an important role in evolving pharmacy  
28 informatics beyond its current state to one with a clinical edge, centered on analytics and  
29 delivering information and knowledge at the point of care. The ABMS decision may also impact  
30 the development of a standardized, interprofessional educational roadmap for individuals  
31 seeking a career in pharmacy informatics.<sup>7-9</sup>

### **Roles and Responsibilities**

32 Pharmacists who practice clinical informatics must collaborate with other healthcare and  
33 information technology professionals to promote the safe, efficient, effective, timely, and  
34 optimal use of medications. They contribute to the transformation of healthcare by analyzing,  
35 designing, implementing, maintaining, and evaluating information and communication systems  
36 that improve medication-related outcomes and strengthen the pharmacist-patient relationship.  
37 The role of a pharmacy informatician revolves around their knowledge of pharmacy practice,  
38 safe medication use, clinical decision-making, and improving medication therapy outcomes,  
39 combined with their understanding of the discipline of informatics and HIT systems.<sup>10</sup> Their  
40 primary roles and responsibilities must encompass five broadly defined categories:

41       Data, information, and knowledge management - Managing medication-related information  
42       while promoting integration, interoperability, and information exchange.

43       Information and knowledge delivery - Delivering medication-related information and  
44       knowledge throughout the clinical knowledge lifecycle, from the point of knowledge  
45       generation through cataloging, embedding knowledge into the workflow, and measuring  
46       the usage and effectiveness of that knowledge.

47 Practice analytics - Developing point-of-business analytic solutions for improving decision-  
48 making.

49 Applied clinical informatics - Applying user experiences, research, and theoretical  
50 informatics principles to improve clinical practice and usability.

51 Leadership and management of change - Leading and participating in the procurement,  
52 development, implementation, customization, management, evaluation, and continuous  
53 improvement of clinical information systems.

54 **Data, information, and knowledge management.** Pharmacy informaticists play a key role in  
55 maintaining the data, information, and knowledge assets across all systems that support  
56 medication management. They are instrumental in ensuring data quality and safety, minimizing  
57 data quality risks, and affirming medication-related data, information, and knowledge  
58 management best practices.<sup>10, 11</sup> Data quality and information management best practices  
59 encompass:

- 60 • Providing the appropriate level of data governance and stewardship.
- 61 • Adopting standard human and machine interpretable formats.
- 62 • Utilizing controlled terminology for integration and interoperability.
- 63 • Ensuring that data are accurate, accessible, complete, consistent, current, timely,  
64 precise, at appropriate level of granularity, reliable, relevant, conforming, and  
65 understandable across all data quality management domains.
- 66 • Ensuring consistent use of maps to internal and external standards and reference  
67 data.
- 68 • Ensuring that system architecture supports data interchange.
- 69 • Ensuring that data, information, and knowledge are audited, measured, and  
70 evaluated for effectiveness.
- 71 • Ensuring that data, information, and knowledge assets are validated, integrated,  
72 normalized, consolidated, and routinely optimized.
- 73 • Developing infrastructure for knowledge, metadata, and terminology management.

- 74 • Ensuring that information is readily and rapidly understood and accessed within the  
75 workflow.
- 76 • Ensuring that information and knowledge are centrally managed, collaboratively  
77 developed, and easily disseminated and maintained.
- 78 • Ensuring that information and knowledge are platform-independent.
- 79 • Developing tools to effectively maintain and manage data, information, and  
80 knowledge.

81 Maintenance roles and responsibilities include:

- 82 • Corrective maintenance – Taking corrective and educative steps required to correct  
83 problems with the utilization of a clinical information system or technology.
- 84 • Customized maintenance - Modifying features already in production systems that  
85 require updating or modification for user needs. Customized maintenance is essential in  
86 clinical information systems, as healthcare is constantly changing (e.g., with new drugs,  
87 new treatment guidance, new procedures).
- 88 • Enhancement maintenance -Improving the performance of applications and people  
89 associated with the use of tools.
- 90 • Preventive maintenance - Taking steps in advance to reduce the risk of a problem that  
91 includes testing prior to a new release or system upgrade.<sup>12</sup>

92 **Information and knowledge delivery.** Healthcare delivery is inherently complex and  
93 knowledge-dependent, and it is becoming ever more challenging for providers to absorb and  
94 assimilate the growing volume and granularity of knowledge needed for safe and effective  
95 patient care. The clinical knowledge available is often conflicted, misaligned, and not readily  
96 identified or available at the point of care. To serve the needs of any clinical encounter,  
97 relevant patient-centered knowledge must be accessible to the person supplying care at the  
98 right time in the workflow. Such knowledge can be delivered proactively (before decisions are  
99 made), interactively (as decisions are made), or asynchronously or passively as reference  
100 information that can be searched online. Pharmacy informatics plays a key role in supporting  
101 and overseeing the core processes involving information and knowledge delivery throughout  
102 the clinical knowledge lifecycle. This role includes knowledge discovery and creation,  
103 knowledge application and delivery, and knowledge asset management.

104           **Knowledge discovery and creation.** As technology-driven transactions for results,  
105 ordering, documentation, task completion, communication, and patient monitoring continue to  
106 grow, so will the amount of data. Pharmacy informatics plays a key role in analyzing these data  
107 for the purpose of understanding performance; evaluating process; and reporting, predicting,  
108 and harvesting new information to create new knowledge for improving outcomes.

109           **Knowledge application and delivery.** Pharmacy informatics is responsible for leveraging  
110 knowledge at the right time and place within a provider's workflow to improve caregiver  
111 effectiveness, work satisfaction, patient satisfaction, and the quality of care. Pharmacy  
112 informatics must continue to evolve to optimize clinical decision support use and develop tools  
113 that reduce information overload and provider burden. Pharmacy informatics is responsible for  
114 looking beyond the traditional means of delivering knowledge by analyzing process and  
115 outcomes data from existing applications to develop and implement new solutions for  
116 embedding knowledge into the workflow.<sup>13</sup>

117           **Knowledge asset management.** Pharmacy informatics must play a significant role in  
118 managing and supporting a healthcare system's technology-enabled medication information  
119 and knowledge assets. This role would include assisting with authoring, encoding, cataloging,  
120 versioning, updating, disseminating, and maintaining an inventory of medication-related  
121 information and knowledge. Despite the emergence of commercial content management  
122 systems and groupware, pharmacy informatics must provide the appropriate level of oversight  
123 and governance for these activities and play a role in the development of future knowledge  
124 asset management systems that support end-to-end knowledge engineering.

125           **Practice analytics.** The healthcare industry has historically generated large amounts of data  
126 driven by financial, regulatory, compliance, and patient-care-related activities. These data have  
127 primarily been stored in hard copy form, making it difficult to process through traditional  
128 database management tools. Paper records have also limited opportunities for effective  
129 exchange of information with other healthcare systems or providing actionable insight on  
130 reducing costs, improving performance, and making decisions. The recent infusion of financial  
131 incentives and regulation involving HIT from the American Recovery and Reinvestment Act  
132 (ARRA)<sup>14</sup> has fueled the implementation of technologies across the United States, contributing  
133 to an exponential growth of available and useable healthcare data. Healthcare organizations

134 are looking for every opportunity to transform and leverage data into information that provides  
135 concise, timely, descriptive, predictive, and prescriptive insight into their business and clinical  
136 data. Business intelligence (BI) and analytics (BA) processes and technologies are enabling  
137 health systems to improve their performance and maintain their competitive advantage while  
138 creating an additional demand for clinical informatics professionals. Pharmacy informatics plays  
139 a significant role in all efforts surrounding medication management-related BI and BA activities.  
140 Pharmacy informaticists' understanding of basic software and database design, ability to grasp  
141 the big picture, and functional knowledge of detail, coupled with their analytical skills, create  
142 opportunities to develop evidence-driven answers for practice improvement and performance  
143 questions, such as

- 144 • How are pharmacists performing in relation to cost, quality, and service?
- 145 • How can pharmacists improve performance and safety within and outside their service  
146 lines?
- 147 • How can pharmacy practice identify patients who are at risk for readmission?
- 148 • How can pharmacy practice identify patients requiring medication therapy management  
149 services?<sup>15, 16</sup>

150 Pharmacy informatics roles and responsibilities in BI and BA must include:

- 151 • Ensuring data are standardized, structured, and modeled to support a data-driven BI  
152 and BA culture.
- 153 • Creating effective analytics tools that allow for multiple formats and layers of analysis,  
154 from summary reports for a population of patients to a practice and at the individual  
155 patient-encounter level.
- 156 • Development, maintenance, and quality assurance of clinical, operational, and financial  
157 dashboards, scorecards, screening, and surveillance tools to guide achievement of  
158 treatment and strategic goals.
- 159 • Driving analytics to the front line by creating greater end-user accessibility to BI and BA  
160 tools.
- 161 • Monitoring effectiveness of tools and information to deploy or further develop point of  
162 care or analytical systems.

163 **Applied clinical informatics.** Pharmacy informatics plays a key role in delivering informatics  
164 research principles and best practices to the bedside. Through informal and formal partnerships  
165 with the research community, pharmacy informaticists must work collaboratively with  
166 members of various disciplines to improve the effectiveness, efficiency, and safety of systems  
167 that support medication management. They must actively participate in relevant associations  
168 and workgroups in the clinical informatics field to maintain their current skills and play a  
169 significant role in the following activities:

- 170 • Acquiring professional perspective - Understanding and analyzing the history and values  
171 of the discipline and its relationship to other fields while demonstrating an ability to  
172 read, interpret, and critique the core literature.
- 173 • Analyzing problems - Analyzing, understanding, abstracting, and modeling a specific  
174 biomedical problem in terms of data, information, and knowledge components.
- 175 • Producing solutions - Troubleshooting and effectively analyzing problems to identify and  
176 understand the spectrum of possible solutions and generating designs that capture  
177 essential aspects of solutions and their components.
- 178 • Articulating the rationale - Defending the specific solution and its advantage over  
179 competing options.
- 180 • Implementing, evaluating, and refining - Carrying out the solution (including obtaining  
181 necessary resources and managing projects), evaluating it, and iteratively improving it.
- 182 • Innovating - Creating new theories, typologies, frameworks, representations, methods,  
183 and processes to address clinical informatics problems.
- 184 • Working collaboratively - Teaming effectively with partners within and across  
185 disciplines.
- 186 • Educating, disseminating, and discussing - Communicating effectively to students and to  
187 other audiences in multiple disciplines in persuasive written and oral form.

188 **Leading and managing change.** To ensure that HIT systems support safe and effective  
189 medication use, pharmacy informaticists are expected to lead as well as manage the risks and  
190 changes associated with the development, implementation, safety, and use of systems that  
191 support medication management. Their knowledge and skills in comprehending and evaluating

192 organizational culture, managing change, working effectively in interdisciplinary teams ,  
193 communication, synthesizing user requirements, and articulating HIT needs within the context  
194 of broader strategic goals allow them to play a significant role in

- 195 • Leading health-system, professional, industry, regulatory, standards-setting, and  
196 governmental organizations to sound conclusions regarding the use of technology in  
197 medication management.
- 198 • Leading and managing the evaluation and communication of the potential risks of a  
199 newly implemented technology and developing plans to mitigate potential hazards.
- 200 • Translating user requirements into safe and effective system designs.
- 201 • Implementing project management best practices.
- 202 • Attaining key leadership roles within the healthcare technology industry, professional  
203 practice associations, and healthcare technology organizations.<sup>4, 10, 11</sup>

### Conclusion

204 As the scope for development and complexity of systems that support medication management  
205 continues to grow, so does the need for individuals to lead, manage, and evaluate them. A  
206 pharmacy informaticist is uniquely qualified and possesses the necessary skills to fulfill this  
207 need. Their knowledge of pharmacy practice and safe medication use, combined with their  
208 understanding of informatics concepts, methods, and tools, provide the framework for  
209 effectively leading and participating in the procurement, customization, development,  
210 implementation, management, evaluation, and continuous improvement of clinical information  
211 systems.

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# 2015 Report of the ASHP Treasurer

PHILIP J. SCHNEIDER

Am J Health-Syst Pharm. 2015; 72:1416-8

Each year, the ASHP Treasurer has the responsibility to report to the membership the financial condition of the Society. The Society's fiscal year is from June 1 through May 31, coinciding with our policy development process and timetable. This report will describe ASHP's financial performance and planning for three periods, providing (1) the final audited prior-year numbers (for fiscal year 2014), (2) current-year (fiscal year 2015) projected performance, and (3) the budget for the fiscal year ending May 31, 2016.

ASHP segregates its finances into two budgets, core operations and the development budget. The core budget represents the revenue and expense associated with the core operations of the organization. The development budget is intended for expenditures that are (1) associated with new, enhanced, and expanded programs, (2) associated with time-limited programs, (3) capital asset purchases, or (4) supplemental operating expenses. The program development budget is funded only from investment income.

The audit of the May 31, 2014 financial statements of the Society and the Society's subsidiary, the 7272 Wisconsin Building Corp., performed by the firm of Tate & Tryon, resulted in an unqualified opinion.

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



Copies of the audited statements are available by contacting the ASHP Executive Office.

## Fiscal Year Ending May 31, 2014—Actual

Last year I reported to you that we were projecting a surplus from both core operations and in the development budget. That projection proved true as the Society's net increase in net assets before a pension adjustment totaled \$3.9 million. A \$2.4 million pension adjustment pushed the Society's 2014 net increase in net assets to \$6.3 million. The Society's net assets totaled \$40.5 million at May 31, 2014, 81% of total expense. Our long-term financial policy is to maintain net assets at a target of 50% of total

ASHP and 7272 Wisconsin Building Corp. expenses.

The Society's May 31, 2014, year-end balance sheet (Figure 2) remained impressive, strengthened from the 2014 results from operations. The May 31, 2014 asset to liability ratio stood at 2.96:1.00, up from 2.55:1.00 a year ago.

## Fiscal Year Ending May 31, 2015—Projected

As of February 28, 2015 financial performance in the core budget for the year ending May 31, 2015 is projected to produce a net income of \$1.5 million (Figure 1). A positive performance in the stock market is expected again in fiscal year 2015 helping to produce a development budget surplus of \$240,000.

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Adding the core net income, the development budget surplus and allowing for \$200,000 net asset spending approved by the Board, the Society's total increase in net assets is projected at \$1.5 million. If we achieve these year-end projections as indicated in Figure 1, the Society's net assets at May 31, 2015 will be \$42.0 million, 82% of the total ASHP and 7272 Wisconsin Building Corp. expense.

### Fiscal Year Ending May 31, 2016—Budgeted

The Society's 2016 core budget is essentially a balanced budget (Figure 1) with the core and development budgets combined producing

a \$45,000 surplus (Figure 1) before spending from net assets. Spending from net assets will be for pharmacist provider status initiatives and needed information technology infrastructure upgrades. Although the spending from net assets (\$1.4 million) will cause an overall deficit for 2016, the Society's total net assets are still budgeted to be at a strong 72% of total expense.

### 7272 Wisconsin Building Corporation

The Society's subsidiary, the 7272 Wisconsin Building Corp., finished the 2014 fiscal year on a very positive note, producing net income of \$1.9 million before owner's distribution (Figure 3). The subsidiary owns the

headquarters building and derives income from leased commercial and office space.

### Conclusion

As your Treasurer, I am pleased to be a part of a Board of Directors that is committed to advancing and supporting the professional practice of pharmacists in hospitals and health systems. I can say with confidence that ASHP continues to be a strong and vibrant organization from both a membership and financial viewpoint. With its strong financial resources, with a proactive Board and membership and with a very dedicated CEO and staff, ASHP is well positioned to meet the needs of the membership.

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

	Actual Fiscal Year Ended May 31, 2014	Projected Fiscal Year Ended May 31, 2015	Budget Fiscal Year Ended May 31, 2016
<b>CORE OPERATIONS</b>			
Gross revenue	\$ 43,773	\$ 44,767	\$ 45,613
Total expense	(43,819)	(44,705)	(47,706)
Earnings from subsidiary	1,877	1,300	2,000
Investment income subsidy	109	102	102
<b>Core Net Income</b>	<u>\$ 1,940</u>	<u>\$ 1,464</u>	<u>\$ 9</u>
<b>PROGRAM DEVELOPMENT</b>			
Investment income	\$ 3,496	\$ 1,944	\$ 1,311
Program expenses	(1,457)	(1,704)	(1,275)
<b>Program Development Net Income</b>	<u>\$ 2,039</u>	<u>\$ 240</u>	<u>\$ 36</u>
<b>Programs Funded from Net Assets</b>	\$ (29)	\$ (200)	\$ (1,400)
<b>Increase in Net Assets</b>	\$ 3,950	\$ 1,504	\$ (1,355)
Pension Plan Adjustment	2,396	—	—
<b>Net Increase in Net Assets</b>	<u>\$ 6,346</u>	<u>\$ 1,504</u>	<u>\$ (1,355)</u>
<b>Net Assets Beginning of Year</b>	\$ 34,191	\$ 40,537	\$ 41,738
<b>ASHP Net Income</b>	6,346	1,504	(1,355)
<b>Net Assets End of Year</b>	<u>\$ 40,537</u>	<u>\$ 42,041</u>	<u>\$ 40,383</u>
<b>% of Total Expense</b>	81%	82%	72%

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

	Actual as of May 31, 2014	Actual as of May 31, 2013
<b>ASSETS</b>		
Current assets	\$ 4,200	\$ 3,504
Fixed assets	\$ 1,107	\$ 1,269
Long-term investments (at market)	\$ 49,602	\$ 45,997
Investment in subsidiary	\$ 6,115	\$ 5,358
Other assets	\$ 216	\$ 172
<b>Total Assets</b>	<u>\$ 61,240</u>	<u>\$ 56,300</u>
<b>LIABILITIES</b>		
Current liabilities	\$ 15,590	\$ 14,985
Long-term liabilities	\$ 5,112	\$ 7,124
<b>Total Liabilities</b>	<u>\$ 20,702</u>	<u>\$ 22,109</u>
<b>NET ASSETS</b>		
Net assets	\$ 40,537	\$ 34,191
<b>Total Net Assets</b>	<u>\$ 40,537</u>	<u>\$ 34,191</u>
<b>Total Liabilities and Net Assets</b>	<u>\$ 61,240</u>	<u>\$ 56,300</u>

Figure 3. 7272 Wisconsin Building Corporation (ASHP subsidiary) statement of financial position and statement of activities for fiscal year 2014 (in thousands).

	Fiscal Year Ended May 31, 2014		Actual As of May 31, 2014
<b>REVENUE AND EXPENSE</b>		<b>ASSETS</b>	
Gross revenue	\$ 7,111	Current assets	\$ 2,504
Operating expense	\$ (4,735)	Property and plant (net)	\$ 17,489
<b>Operating Income</b>	<u>\$ 2,376</u>	Other assets	\$ 2,246
		<b>Total Assets</b>	<u>\$ 22,239</u>
Provision for income taxes	\$ (499)	<b>LIABILITIES</b>	
<b>Increase in Net Assets</b>	<u>\$ 1,877</u>	Current liabilities	\$ 1,623
		Mortgage payable	\$ 13,925
Owners distribution and capital contributions	\$ (1,120)	Other liabilities	\$ 576
		<b>Total Liabilities</b>	<u>\$ 16,124</u>
<b>Net Increase in Net Assets</b>	<u>\$ 757</u>	<b>NET ASSETS</b>	
		Net assets	\$ 6,115
		<b>Total Net Assets</b>	<u>\$ 6,115</u>
		<b>Total Liabilities and Net Assets</b>	<u>\$ 22,239</u>



# House of Delegates

## Recommendations from the 2015 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. **Revise ASHP Position (0610), “Pharmacist’s Right of Conscience”**

Nicole Allcock (MO)

**Recommendation:** ASHP should revise position 0610 to remove the requirement of referral and replace it with “transfer care” in order to place decision making regarding ethically troubling therapies in the hands of the patient and remove the burden of cooperation on the part of the pharmacist.

**Background:** ASHP’s current statement on Pharmacist’s Right of Conscience does not protect the pharmacist from cooperating in actions which are ethically troubling. Referral by a pharmacist to another specific pharmacist is still considered cooperation. Given the current political climate in the United States, this puts pharmacists of conscience in danger of lawsuit, loss of income and loss of license. ASHP should change this policy to better support ALL pharmacists, without excluding or alienating those who wish to follow their conscience.

### 2. **Specific Gravity Data**

Robert Granko (NC)

**Recommendation:** Ask manufacturers to provide specific gravity for IV products to promote utilization of gravimetric analysis.

**Background:** This is required for IV robots.

### 3. **Need to Update ASHP Guidelines on Providing Pediatric Pharmaceutical Services**

Kim Benner (AL)

**Recommendation:** It is time to update the 1994 statement on providing pediatric pharmaceutical services as the health care model has changed for the care of pediatric patients in a health system.

**Background:** There is a practice need for this guideline that addresses requirements for health systems that care for pediatric patients. A working group of SCSS members drafted an update of this guideline from 2011-2013 but forward progression at the organization has been stagnant. We request that ASHP devote staff manpower to bring these in progress draft guidelines forward for adoption as a permanent guideline to assist our healthcare systems.

### 4. **Definition of Medication History and Medication Reconciliation**

Wes Pitts, Kristie Gholson (MS)

**Recommendation:** Develop standard definitions for “medication history” and “medication reconciliation” and promote proper use of each.

**Background:** Many times the terminology of “medication history” and “medication reconciliation” are used interchangeably. Clearly, these are two completely different processes. The establishment of standard definitions would help clarify these functions when being discussed within the pharmacy profession and with other professions/administrators.

**5. Survey and Distribute to Members Employment and Salary Information Broken Down by City, State and Job Function; Discuss Trends in the Supply and Demand of Pharmacists**

John Quinn (DC)

**Recommendation:** One commonality of all ASHP members is interest in their careers and trends within the profession. This is especially true today where we see an oversupply of pharmacists in some markets. ASHP is in a unique position to find and interpret market trend information and to take a leadership role in a conversation about future supply of pharmacy professionals.

**Background:** One challenge for ASHP is for it to be a relevant and important tool for all health system pharmacists. As the scope and specialization of practice has changed there are fewer subjects that will be of interest to all members. ASHP is a national leadership organization and should be out in front of large issues including the education of pharmacy professionals and the careers of these professionals. The supply of pharmacists is controversial with members and other stakeholders having different perspectives. It is however of interest to all members. A survey by ASHP of salaries and employment trends by city, state and specialty would be a helpful to members and start a healthy discussion about supply and demand of pharmacy professionals.

**6. Increased Financial Support for Local Affiliates To Send Representatives to the ASHP House of Delegate Meetings**

John Quinn (DC)

**Recommendation:** That ASHP increase the stipend to support local affiliates who attend the ASHP House of Delegates.

**Background:** The Washington D. C affiliate respectfully asks that ASHP consider increasing the stipend to support local affiliates who attend the ASHP House of delegates.

**7. Affordability of Medications Task Force**

Jerome Wohleb (NE sponsored) (State supported: NE, AZ, CO, OR, MN, CA, ID, CT, IL, UT, WA, VA, RI, LA, DC, MA, MD, ME, SD, PA, KY, WA, WI, OH, TN, MT, SC, VT) (One delegate: NH, MI, DE, FL)

**Recommendation:** ASHP to appoint a task force to address the affordability of medications in conjunction with other organizations (e.g. AARP, AMCP, APhA, AHIP, etc.).

**Background:** New brand-name drugs are often expensive. Recently, certain older drugs (including generics) have also become prohibitively expensive. The task force should develop strategies to address parity in pricing, potential legislation, reimbursement, affordable price-sharing and other issues that impact patient access and adherence due to cost.

## 8. Epidural Steroid Injections

Emily Dyer (VA)

**Recommendation:** To advocate for pharmacist oversight of medications used during epidural steroid injection procedures.

**Background:** Epidural Steroid Injections are a growing treatment for different types of back pain, but currently there are no approved medications (steroids, anesthetics) to be used in epidural steroid injections. Steroids have different particulate counts and some anesthetics can cause death if given inappropriately. Sometimes the benefits do not outweigh the risks. My father actually died from receiving an epidural steroid injection and there isn't much literature published on all the adverse events that can occur.

## 9. Developing Educational/Training/Guidance Materials for the New Role of Pharmacy Technicians as Medication History Technicians

Tricia Meyer (TX)

**Recommendation:** To supplement the current ASHP website for medication reconciliation materials with specific information to further develop the pharmacy technician's role in taking patient medication histories. This should include information on communication skills, interview skills to help determine patient compliance, and how to manage barriers during the interview.

**Background:** As we expand the role of the pharmacy technician according to the PPMI recommendations, pharmacy technicians will need proper training to perform the new duties. ASHP can be the central repository of information as a tool kit for conducting patient admission medication interviews.

## 10. Regulation of Dietary Supplements

Denise Fields, Jennifer Phillips, Steve Riddle (IN, IL, WA)

**Recommendation:** That ASHP increase advocacy efforts around dietary supplements by collaborating with Congress, other healthcare organizations and patient advocacy groups with the goal of amending the Dietary Supplement Health and Education Act or enacting other legislation that ensures the safety and integrity of dietary supplements.

**Background:** ASHP currently has a position statement on dietary supplements that was drafted in 2004 that urged for improvements to the DSHEA. However, to date, this desired action has not been realized. In recent years, there has been increased focus on patient safety. Ensuring the integrity of products created via sterile compounding is one example. There are many safety issues associated with dietary supplements. Therefore, it would seem appropriate and timely for ASHP to champion efforts to reevaluate the DSHEA and its impact on public safety. While dietary supplements may be beneficial, they are not without risk. Widespread and indiscriminate use of dietary supplements presents dangers to public health. Evidence of variability in dietary supplement content has spurred efforts to standardize products. A more serious trend today is extra ingredients in supplements. Some “herbal” supplements have been found to contain prescription drugs or other compounds that are not listed on their labels. Although DSHEA does require that dietary supplements be safe, it does not require prospective testing to ensure safety. To remove a product from the market, FDA must prove the product is unsafe. Under DSHEA, some dietary substances that were banned from the US market because of concerns about their safety have been allowed to return. In reviewing policy and guidance statements from a variety of organizations, the following legislative goals should be strongly recommended. 1. All dietary supplements, including those currently in the marketplace, must undergo FDA evaluation for evidence of safety and efficacy prior to approval; 2. All dietary supplement labeling must include full disclosure of all product components and their source with associated strengths as well as describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; 3. All dietary supplement manufacturers adhere to the development and enforcement of required dietary supplement good manufacturing practices (GMPs) and compliance with USP/NF standards to ensure quality safe, contaminant-free products; 4. Remove promptly unsafe, adulterated or ineffective dietary supplement products from the market.

#### 11. **Sharing and Obtaining Medication Histories Through Transitions of Care**

Christi Jen (AZ)

**Recommendation:** For ASHP to advocate for the education of pharmacists and pharmacy technicians, and increased awareness on HIPAA Patient Privacy laws as they pertain to obtaining and sharing medication histories to facilitate the medication history process and ensure optimal and safe care through transitions of care.

**Background:** All too often, patients present to the emergency department without accurate medication histories, and healthcare providers need this list in order to provide optimal and safe patient care. Pharmacists, pharmacy technicians, and other healthcare providers look to community pharmacies and other hospitals to obtain this information and are met with resistance because obtaining and sharing medication history information is misconstrued as violating the HIPAA Patient Privacy Law. Many community pharmacies will reject a request to obtain a medication history because of this misinterpretation, despite the fact that this information is being obtained for the continuity of care of the patient being admitted to the hospitals. CMS has now required that Heart Failure patients have an admission and discharge medication reconciliation completed. Many readmissions are also associated with poor medication histories and reconciliation, or lack thereof. Thus, it is recommended that ASHP advocates for the education of the pharmacists and pharmacy technicians, so that optimal patient care is not delayed when there is no up-to-date medication history available. Perhaps, ASHP may work with NACDS and other organizations in order to jointly advocate this practice to ultimately optimize patient care.

**12. Amendment to ASHP Policy 1519, Pharmacy Technician Training and Certification**

Lonye Finneman (MT, AZ, WI, MI, NE, SD)

**Recommendation:** Council on Education and Workforce Development consider an additional statement to the newly revised policy on Pharmacy Technician Training and Certification to advocate that pharmacy technicians initially obtain Pharmacy Technician Certification Board certification and that a mechanism be in place to maintain competency (such as state licensure or certification).

**Background:** When the policy was recently revised in the House of Delegates, the section related to advocating for pharmacy technicians to obtain initial Pharmacy Technician Certification Board certification was removed due to concerns of requiring PTCB certification maintenance being duplicative in some states that require specific CE for licensure already. Unfortunately, removing this statement also removed ASHP policy on advocating for initial pharmacy technician certification, as well as a mechanism for maintaining competency. The mechanism may differ from state to state, but it is critical that a mechanism be in place whether through state licensure or continual certification or other mechanisms.

**13. Use of Meeting Technology for Section and SAG meetings**

Dan Degnan (Section of Inpatient Practitioners)

**Recommendation:** That ASHP make available web-based meeting technology for ASHP Section and SAG meetings.

**Background:** The SICP SAG satisfaction survey reviewed at the Section Executive committee revealed that members would like to share documents and other information during their regular online meetings. The recommendation is in response to the survey. Currently members use their own company's meeting technology for these meetings and it leads to inconsistent use.

**14. Development of Residency Models in Small and Rural Health Settings**

Dan Degnan (Section of Inpatient Care Practitioners)

**Recommendation:** That ASHP foster the development of viable residency models in small and rural health settings with consideration for both the cost and quality of such programs.

**Background:** Provider status bill and recent working relationships with NRHA provide ASHP a great opportunity to develop models either through telepharmacy or flexibility regarding accreditation standards to enhance these types of opportunities.

**15. Policy on Equitable Care**

Annet Arakelian (CA)

**Recommendation:** Recommend ASHP develop a policy to promote, support, and advocate for developing a diverse workforce and addressing gaps in healthcare, including but not limited to race and ethnicity but also other gaps such as socioeconomic and literacy.

**Background:** ASHP has a statement on racial and ethnic disparities in health care that describes the disparities and opportunities for pharmacist and pharmacy profession. However, we have no policy on record to promote and advocate for developing workforce and identifying best practices that close disparities in care. The policy will allow ASHP to develop programs and services, and recognize successful practices.

**16. Specialty Pharmacy Service Center**

Ross Thompson (MA)

**Recommendation:** ASHP to develop and maintain a service to support ongoing management of specialty pharmacy service delivery provided by health systems.

**Background:** Specialty pharmacy industry is expanding and evolving rapidly. Most ASHP members' practice sites would benefit from a centralized support service that would monitor changes in policy and new drug technology to allow health systems to prepare for implementation of these changes as they emerge.

**17. Education of Members on 503A and 503B Regulations and Entities**

Ross Thompson and Ernie Anderson (MA)

**Recommendation:** Recommendation that ASHP educate its members on all aspects of 503A and 503B compounding pharmacies and provide a tool to vet such facilities which members can utilize to ensure medication safety, further to educate members on the utilization of 503B facilities as an option to meet various patient care needs for sterile products by health systems.

**Background:** The DSCSA of 2013 created 503A and 503B compounding entities under the FDA largely in response to the New England Compounding tragedy. Regulations are still being determined and will be coming out over the next several months. Education must be continuous as the regulations are promulgated. The new entities under 503A and 503B with FDA oversight are new arenas for pharmacists. Pharmacists must be educated on the regulatory differences between these two types of designations. There are over fifty 503B facilities in the US for manufacturing sterile IV products. Pharmacists need tools to vet these facilities to ensure patient safety. These facilities may be helpful to health-systems to address sterile products needs for their patients including outsourcing when the hospital does not have a USP 797 clean room and the 503B facilities manufacturing of drugs on the drug shortage list to meet patient needs. These 503B facilities may have beyond use dating that is longer than the dating the health system pharmacy can apply. The 503B facilities under the FDA are cGMP manufacturing with required quality control testing procedures. Pharmacist members need further education of the requirements of a cGMP facility. This is new territory for health system pharmacists.

#### 18. Antipsychotic Drug Use

Victoria Ferraresi (CA)

**Recommendation:** That ASHP support efforts to prevent the inappropriate use of antipsychotics in nursing home and other care settings but also advocate that this not interfere with their appropriate use of prevent patients needing these medications from residing in nursing homes.

**Background:** 1. Antipsychotics are frequently prescribed to dementia patients in nursing homes and other care settings despite the lack of the use of dementia as an official indicator for use and with black-box warnings on serious risks. 2. Effective February 20, 2015, the Centers for Medicare and Medicaid (CMS) made changes to nursing home compare to add antipsychotic drug use to the Quality Measures star ratings; having residents taking antipsychotics will lower a facility's star ratings. 3. Anecdotal reports are surfacing across the country that nursing homes are refusing to allow the use of antipsychotics for any indication and further are refusing admission to individuals receiving these medications. 4. The January 2015 Government Accountability Office (GAO) report, "Antipsychotic Drug Use: HHS has Initiatives to Reduce Use Among Older Adults in Nursing Homes, But Should Expand Efforts to Other Settings" suggests reducing antipsychotic use in hospitals and other care settings.

[www.gao.gov/assets/670/668221.pdf](http://www.gao.gov/assets/670/668221.pdf). 5. Efforts to stop inappropriate antipsychotic use should be balanced with permitting appropriate medical uses in treating conditions such as schizophrenia, bipolar disease, delirium, etc., in all care settings.

#### 19. Hazardous Medication Identification

Kathleen Donley, Margaret Huwer, Karen Kier, Scott Knoer, Julie Zaucha (OH)

**Recommendation:** At the request of Rob Mains, we recommend that ASHP advocate for the FDA capture and maintenance of the accurate identification of hazardous medication products in the structured product label of the FDA daily med database.

**Background:** In support of the NIOSH and proposed USP 800 recommendations for handling hazardous medications, we need accurate identification of products containing these ingredients. The current system does not currently identify hazardous medications.

## 20. Electronic Voting

Carol Rollins (AZ, IL, ID, CO, MT, MI, WA, CT)

**Recommendation:** Recommend the ASHP use electronic voting for all votes in the House of Delegates.

**Background:** In the first HOD 2015, there was at least one vote that I question whether a quorum voted. Electronic voting would document the total number of votes cast and allow the chair to give more time for decisions. In addition delegates vary in their strength of response such that some voice votes may not accurately reflect the numbers responding yay or nay. Electronic voting would provide an accurate vote not dependent on the strength of an individual's voice vote. In addition, it would provide a clear record of the strength of support or disagreement for a given policy. Policies with marginal passage might then be reviewed sooner than strongly supported policies. Time has previously been the barrier to electronic voting. With newer technology with more rapid response and more discussions now done pre-HOD meeting, the benefits of electronic voting now seem to outweigh potential barriers.

## 21. Using Indianapolis as a Host Site for a Future Summer Meeting

John Hertig (IN)

**Recommendation:** That ASHP consider Indianapolis, the host of Super Bowl 46 and numerous amateur sporting events, as a future site for the ASHP Summer Meeting.

**Background:** This request has been made in the ASHP House of Delegates numerous time and each year the Indiana delegation has responded with information requested by ASHP regarding Indianapolis weather, hotel room inventory, area recreational activities and other considerations that seen to be used in the selection process.

## 22. Improved FDA Management of Medication Structured Product Data

Kevin Martin (VT)

**Recommendation:** We recommend that ASHP advocate for the FDA to take greater ownership of the maintenance of the Structured Product Label (SPL) database contents with regards to: 1. Maintenance of accurate and unique identifiers for each product/product ingredient 3. Enforcement of accurate coding of the standardized data elements in the SPL, 4. Integration of the SPL with RxNorm, and 5. Direction to the industry on how quickly SPL data updates should be made available within EHR systems.

**Background:** The Structured Product Label (SPL) data provided by the FDA is used by all drug database vendors as the basis for their prescribing and medication reconciliation databases used in EHR's. Problems with missing data, reuse of identifiers with new products and incomplete integration with RxNorm results in problems maintaining medication compendia databases. In addition there is no direction to software vendors and healthcare facilities on what is a reasonable delay for prescribers to see SPL updates propagated to the EHR prescribing and medication reconciliation drug compendia databases. In fact there is currently no EHR certification criteria specifying update requirements for the drug compendia used for e-prescribing and medication reconciliation. This recommendation will support more accurate drug compendia databases that are easier to maintain and more timely with applied updates.

**23. Criteria and Education for Appropriate Use of Drugs with Abuse Potential**

Michael Dickens (ID), Julie Nelson (TX), Elizabeth Thompson (ID), Diane Fox (TX)

**Recommendation:** We recommend that ASHP in cooperation with medical organizations develop criteria for appropriate prescribing and monitoring of refills for drugs with abuse potential (i.e., opiates, sedative hypnotics, skeletal muscle relaxants and stimulants, and anxiolytics).

**Background:** Abuse of prescription medications is a national problem. Prescriptions that are FDA approved for short term symptomatic relief (e.g.: pain, anxiety, insomnia, etc.) often are refilled well beyond the approved treatment time period. Per Jamie Heywood's opening session address, we need to continuously evaluate these patients and their relative need. Many states do have prescription monitoring programs but the focus appears to be on quantity dispensed rather than quality of prescribing and appropriate assessment. Developing criteria would ensure that those who have a legitimate need would continue to remain on therapy, whereas those who do not meet the criteria do not continue to get refills of these medications. If ASHP and the medical societies can provide appropriate criteria and help educate the prescribers, the supply and demand for these medications would be more closely in balance.

**24. Task Force on Pain Management and Opioid Analgesic Access, Use and Abuse**

Steve Riddle, Patricia Gunwald, Denise Fields, Julie Nelson, Rich Pacitti, Joan Kramer, Diane Fox, Vicky Ferraresi (WA, MD, IN, TX, PA, KS, TX, CA)

**Recommendation:** Recommend that ASHP create a task force to examine critical national issues related to pain management and opioid analgesic access, use and abuse and that this group engages internal and external stakeholders with a goal of optimizing ASHP policy positions and advocacy efforts.

**Background:** Proper treatment of acute and chronic pain is a basic patient right and chronic pain represents a significant public health issue with tremendous economic, social, and medical costs. There has been a significant increase in the use of opioid analgesics for pain control with a corresponding growth in the rate of abuse, misuse, and overdose with these drugs; adversely effecting access to opioid analgesics for legitimate and appropriate treatment. Legal, regulatory, licensing and other third party activities intended to control misuse and diversion are having the unintended consequences of impacting effective pain management across the care continuum. ASHP has addressed a number of these issues via policy development; however, considering the scope of the problem, the fragmented approach of creating policies via distinct councils may be leading to the existence of policy gaps, redundancies and conflicting positions. A more global evaluation by ASHP of the current issues related to pain management and opioid analgesic access, use and abuse will help to better identify the scope of the issues, allow a review of current policies, direct better policy alignment and development of new policies, and inform consideration for advocacy efforts and other activities.

**25. Establishment of Ongoing Online Preceptor Development Courses**

Kathy Donley (OH)

**Recommendation:** That ASHP develop ongoing online preceptor courses to enable smaller hospitals to meet the requirements of the residency accreditation standards.

**Background:** The OSHP Residency Expansion Task Force identified that smaller hospitals with limited resources see quality preceptor development as a major barrier to establishing residencies. Establishment of a readily available source of online preceptor development for preceptors at all levels (new to experienced) would remove a major barrier to increasing residency sites at a wider variety of locations.

**26. Revise ASHP Position 9915 to Oppose Pharmacists' Participation in Assisted Suicide**

Nicole Allcock (MD), Desi Kotis (IL), Kevin Colgan (Past President), John Pastor (MN), Kristi Gullickson (MN), Peggy Malovith (MI), Joel Hennenfent (MO), Daniel Good (MO)

**Recommendation:** ASHP should revise Position 9915 to clearly oppose pharmacists' participation in Assisted Suicide on the basis that it is not consistent with the pharmacists' role in affirming life and assisting patients in making the best use of medications.

**Background:** ASHP has stated "The basic tenet of the profession is to provide care and affirm life," and The Code of Ethics for Pharmacists states that "Pharmacists are health professionals who assist individuals in making the best use of medications." Assisted suicide and euthanasia in any situation cannot be intellectually or morally justified as the best use of medications. ASHP's current position on assisted suicide is also in opposition with those of medicine and nursing associations.

**27. Chair-elect and Treasurer-elect Years**

Mark Woods, Phil Schneider (Past Presidents, BOD)

**Recommendation:** To study the feasibility of sequencing the elections of the treasurer and chair of the house so as to allow for treasurer-elect and chair-elect periods around the board table.

**Background:** Unlike members of the Board of Directors and Presidential Officers, newly elected treasurers and chairs of the House become immediate members of the Board. We believe these newly elected board members may benefit from the observation and information exchange that would occur during an "elect" year around the Board table and would suggest this to be evaluated.

**28. Electronic Voting on Political, Religious, or Culturally Sensitive Topics in the House.**

Dave Weetman (IA, WI, AZ)

**Recommendation:** Request that "clicker only" voting be considered when the House of voting on a topic of politically, religious, or culturally sensitive nature, such as capital punishment, abortifacients, medical marijuana, or assisted suicide.

**Background:** None.

**29. CMS Medication Billing Coding Requirements**

Jeanne Ezell (TN)

**Recommendation:** Recommend ASHP advocate for changes in CMS medication billing coding to reduce the complexity and confusion involved particularly with units for various dosage strengths and forms of medications.

**Background:** Although ASHP has provided very helpful educational programming to help members navigate some of the intricacies involved with CMS billing and reimbursement requirements, much time and confusion occurs all across the U.S. with pharmacy and revenue cycle staff in trying to set up CDMs correctly and enter required codes and units in pharmacy information systems. Some units seemed to have been set without any logic involved. Given the expected move away from fee for service toward bundled payment, it would appear to be a good time to advocate major changes in medication billing codes.

*2015 Report of the President and Chair of the Board*

# ASHP: Setting the standard for the future of pharmacy practice

CHRISTENE M. JOLOWSKY

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Today, I want to start with a heartfelt thank you. As my presidential year draws to a close, it is hard to express how grateful I am for the opportunity to have served ASHP and its 43,000 members as president. I also wish to express my thanks to you as members of the House of Delegates for all that you do for ASHP, for our profession, and for patients.

Everything that you have done all year to shepherd ASHP policies through to completion, along with the ongoing work of ASHP's Councils, Sections, Forums, and State Affiliates, shows your commitment to and how focused you are on improving patient care and the future of pharmacy.

On behalf of the Board of Directors, I also want to thank Dr. Abramowitz for his support and leadership throughout this year. His cheerful presence and leadership have made this year a true pleasure. Thank you, Paul.

In my inaugural address, I talked about pharmacists as the constant in the patient care equation. There is no other healthcare professional who is more omnipresent and valuable in

*ASHP could not be the vibrant organization it is or offer the types of meaningful support to members that it does without the heavy lifting that our members do!*



every care transition and practice setting than the pharmacist.

Over the past year, I have had the privilege and opportunity to see that in action, as I met with seasoned practitioners, residents, student pharmacists, and pharmacy technicians all over the country. These visits have shown me how far pharmacy practice is advancing across the continuum of care, and the policies endorsed by this House reflect the diversity of how we practice. We are following the whole life of the patient, and we are on the cusp of big

changes with provider status on the horizon.

Today, I want to share with you a few updates on the ways that ASHP is both driving and reflecting changes in practice, engaging with a new generation of pharmacy practitioners, expanding pharmacy training and certification opportunities, and advocating on the issues that you care about most.

### Updating ASHP's strategic plan

One of the key ways that ASHP ensures that we are all "pulling in the

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same direction” to improve patient care, public health, and practice advancement is through our strategic plan. In 2012, ASHP created a new comprehensive plan that addressed every facet of the organization and included strategic priorities in three key areas: (1) our patients and their care, (2) members and partners, and (3) people and performance.

This strategic plan has served us exceptionally well and has been a valuable tool to communicate ASHP’s priorities to members, stakeholders, staff, and others. This year, the ASHP Board of Directors added three new goals to the plan: (1) advancing patient care and pharmacy practice in small, rural, and underserved settings, (2) addressing the needs and interests of pharmacists who practice in multihospital systems, and (3) helping members address issues related to specialty pharmacy.

We know that pharmacy practice in small, rural, and underserved settings is often a unique and rewarding career track, and we are working to find new ways to support members who work in these areas and help them engage with ASHP. Members who practice in multihospital systems have interests and concerns that arise out of the diversity of care that is offered in these settings, and ASHP is working to ensure that their needs are served as well.

Finally, members who work in the area of specialty pharmacy need our support as well, and this addition to the strategic plan ensures that we will find new and exciting ways to help them succeed in this practice area.

### **Privileging and credentialing**

ASHP has long recognized the value of specialty certification in providing advanced patient care services. You can see our commitment everywhere—in our petitions for new specialties to the Board of Pharmacy Specialties (BPS) and in our policies,

member services and resources, and professional practice initiatives.

In a team-based healthcare environment that is focused more than ever on quality and outcomes, it is clear that the number of practitioners who wish to pursue credentialing and licensure will only grow. ASHP has been active since BPS was founded in 1976 to support petitions for new and emerging specialty certification programs. We were the original petitioners for the oncology and psychiatric specialties and partnered with the American Society of Parenteral and Enteral Nutrition to seek a pharmacy specialty in nutrition. In recent years, ASHP petitioned for certifications in ambulatory care, pediatrics, and critical care.

In the past few years, ASHP has served on the BPS Framework Steering Committee to help evolve and advance the role that specialty certification plays in moving healthcare and pharmacy practice forward. ASHP has also created BPS recertification and review courses in pharmacotherapy, oncology, and ambulatory care and new courses in critical care and pediatric pharmacy.

Our goal with these programs is to help advance pharmacy practice by training pharmacists in these and a growing number of other specialty certification areas. We believe that these programs complete our core strengths in education and residency accreditation and that these are the best programs available to help pharmacy practitioners get to the next level.

ASHP has always been, and will continue to be, a leader on the issue of enhanced credentialing.

### **Speaking to a new generation**

In 2013, we celebrated the 50th anniversary of ASHP accreditation of pharmacy residency programs and the 30th anniversary of ASHP accreditation of pharmacy technician programs. I’m happy to report that we are continuing on an upward

trajectory in terms of the number of residency and technician programs that we have accredited.

When ASHP leaders expressed their vision for pharmacy residency training and started accrediting pharmacy residencies, there were only a handful of programs in existence. I’m excited to report that in the past three years, the number of positions has increased by 1000, or 25%. This exponential growth and demand, along with the dramatic advancement of pharmacy practice, are amazing, and you are part of them.

I’m also pleased to report that more than 3600 pharmacy students and new practitioners matched with a residency position this year. Further, over 300 additional residency positions were added to the 2015 Match. This year’s 8% rate of growth for postgraduate year 1 residency positions exceeded the 5% growth in demand from applicants, which suggests that things are clearly heading in the right direction with regard to expanding residency training.

One of the best parts of being involved in ASHP is seeing the many ways that new practitioners and student pharmacists are changing the profession for the better. Their excitement about the opportunity to provide direct patient care is so inspiring to me, and I’m proud that ASHP continues to be the premier pharmacy organization for this new generation.

But that is not the only way we are helping pharmacy residents and future patient care leaders. ASHP’s Residency Resource Center is a great help to new practitioners. We continue to offer excellent targeted programming at ASHP meetings, and our new *AJHP Residents Edition* debuted in June. This quarterly online supplement to the journal offers pharmacists a fantastic venue to publish the results of projects they completed during their residencies.

We also are planning an advocacy training and legislative day just for

residents in October. This special event comes on the heels of a successful student advocate training and legislative day this past winter. We believe that getting the next generation of pharmacists involved in advocacy on behalf of the profession can only benefit our efforts to achieve provider status. It is also important to engage new practitioners in advocacy as we work to influence and guide other important public health issues such as drug shortages, safe compounding practices, and much more.

### **Member services and engagement**

As a member organization first and foremost, ASHP is focused on ensuring that it provides the resources, services, and support that pharmacists need to be successful in any practice setting. Our Sections and Forums are key avenues of engagement that allow members to get involved in leadership and guide the work of the organization.

Over the past year, ASHP's Sections provided opportunities for more than 500 members to volunteer with advisory groups and committees. This translates into more than 8000 hours of volunteer time in areas such as meeting programming, website content, educational webinars, and editorial input for *AJHP* and other ASHP publications.

ASHP could not be the vibrant organization it is or offer the types of meaningful support to members that it does without the heavy lifting that our members do! It's difficult to adequately express the gratitude that I and other ASHP Board members feel about this tremendous commitment of time, energy, and creative thinking.

This year, ASHP also debuted seven new member resource centers. In addition to the Residency Resource Center I mentioned earlier, we developed new centers on transitions of care, credentialing and privileging,

medication reconciliation, pharmacy technicians, specialty pharmacy, and Ebola. Keeping pace with the issues that matter most to members is one of ASHP's most important endeavors.

### **The importance of advocacy**

Since the 2012 incident at the New England Compounding Center, ASHP has been at the forefront of national efforts to increase oversight of compounding manufacturers while supporting the ability of hospitals and health systems to continue compounding.

That advocacy has paid off; ASHP has become the national voice on safe compounding practices. We are currently working with New Hampshire and Maryland as they work to bridge gaps between state and regulatory requirements for outsourcing facilities created by the Drug Quality and Security Act. We are providing comments to the Food and Drug Administration's newly released guidance documents on compounding that address facility registration, adverse-event reporting, drug repackaging, and a memorandum of understanding with states.

ASHP also has been a longtime leader in the area of antimicrobial stewardship and has long advocated for standardized pharmacy department antimicrobial stewardship metrics to drive improvements in patient outcomes. We offer a vast number of resources, including webinars, traineeships, and Web-based tools, to help members develop stewardship programs within their own organizations.

ASHP was recently recognized for these efforts when the White House invited Paul Abramowitz to its White House Forum on Antibiotic Stewardship on June 2. Paul contributed pharmacists' perspective to this interdisciplinary national discussion on how to best combat the development of superbugs.

ASHP continues its work to battle chronic drug shortages by advocat-

ing on behalf of patients and members. Although new shortages have decreased, the numbers of ongoing shortages we currently see are as high as they were in 2012, the peak year for new shortages. ASHP cohosted a third multistakeholder meeting in late 2014 to further explore what healthcare stakeholders can do to reduce shortages. If you would like to see the recommendations made during the summit, I urge you to read the report online.<sup>1</sup>

Finally, no discussion of advocacy would be complete without a mention of the importance of ASHP's political action committee (PAC) in supporting these efforts. Over the past year, we have seen amazing growth in member support. This is a real shift because, for many years, the ASHP PAC had very few contributions, usually in the range of \$20,000 for each election cycle. This resulted in us being able to support only a limited number of members of Congress who support the interests of our members and the patients they serve.

In the most recent election cycle, however, ASHP members made unprecedented contributions of nearly \$150,000. This allowed us to attend and send more ASHP members to political fundraising events and to support key candidates at higher levels and more candidates overall.

Although this tremendous growth is cause for celebration, we still have a long way to go to grow the PAC even further. ASHP has nearly 43,000 members, and if each member contributed just \$100, we would have a \$4.3 million PAC. At that size, we'd be one of the biggest healthcare PACs in the country, and that would make a tremendous difference to our provider status efforts as well as many other issues that affect pharmacy practice.

These resources help us to broaden our support for pharmacy-friendly congressional candidates and achieve greater awareness of the issues members care about most in the halls of

Congress. If you haven't already contributed to the PAC, I hope you will take the opportunity to do so soon.

### **ASHP Research and Education Foundation**

Before I conclude my remarks today, I want to remind you of the wonderful work conducted by the ASHP Research and Education Foundation. Through its traineeships, grants, and focus on research that highlights the impact pharmacists have on patient care, the Foundation is a critical partner for ASHP in advancing pharmacy practice and healthcare. I urge you to explore the resources that the Foundation has made available for you on its website, and I hope you'll consider giving to this worthy organization.

### **Conclusion**

The leadership you demonstrate here, with your state affiliates, and in your own institutions is critical to ASHP's success and to the successful treatment of patients who depend on pharmacists for safe and effective medication therapies. The policies that emanate from this House are essential building blocks in ASHP's constant effort to expand patient care roles for pharmacists and improve medication use for all patients.

We need you to continue giving of your time, experience, and intellect. We need you to continue to be a member of this great organization. Together, we can really make a difference for patients and advance healthcare in this country.

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*2015 Report of the Chief Executive Officer***Leading the way to transform the profession of pharmacy**

PAUL W. ABRAMOWITZ

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**I**t is my pleasure to report that ASHP has had another spectacular year, and thanks to you—our members—ASHP has remained the leader in advancing pharmacy practice. Whether it was the inaugural Ambulatory Care Summit and meeting in 2014, or this year's first annual Ambulatory Care Conference at the Summer Meetings, ASHP and our visionary members continue to set the pace that others follow.

It is really amazing to think that this December we will recongregate for the 50th anniversary of the ASHP Midyear Clinical Meeting. Just think: 50 years ago ASHP and its leaders had the foresight to recognize that the future of the profession resided in pharmacists working on the patient care unit and in the clinic as highly respected clinical practitioners who take responsibility for the complete medication therapy needs of their patients. I suppose that is not too hard to imagine, given that just 2 years before the first Midyear Clinical Meeting, ASHP started accrediting postgraduate pharmacy residency training and 52

years later has taken residency accreditation and training to new and even greater levels.

I was reminded recently by ASHP's chief executive officers (CEOs) emeriti, Dr. Joseph Oddis and Dr. Henri Manasse, of the various professional and patient care leadership roles ASHP has played throughout our nearly 75-year history. Consider just a few of these roles in addition to clinical pharmacy and residency training: petitioning for most of the

current Board of Pharmacy Specialties certifications, advancing the role of the pharmacy technician, bringing medication safety to the forefront, fostering the safe and effective use of automation and information technology, establishing pharmacy practice and therapeutic standards, conceptualizing the modern pharmacy and therapeutics committee and formulary system, creating the first compounding standards, and many, many more.

*I am absolutely certain that when provider status for pharmacists becomes the law of the land, ASHP members will lead the way in implementing this law.*



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As I mentioned earlier, the Midyear Clinical Meeting celebrates its 50th anniversary this year. It was the first pharmacy meeting focused on clinical pharmacy practice and other cutting-edge patient care-focused topics. Admittedly, that first Midyear, which took place at the Key Bridge Marriott just across the river from Washington, D.C., only had a few hundred registrants. But look at the Midyear Clinical Meeting today, with over 22,000 participants each year and growing, extensive scientific sessions, and opening speakers such as Maya Angelou, Bill Clinton, Colin Powell, and this coming year . . . the 43rd President of the United States . . . George W. Bush and first lady, Laura Bush.

Holding the largest and best pharmacy meeting in the world doesn't happen easily. The success of the Midyear Clinical Meeting speaks to the vision that ASHP and its leaders had about the direction in which pharmacy practice needed to go and their willingness to invest resources for the future of the profession, even if it was going to take decades to nurture and grow them into the success we see today.

I sometimes think that ASHP doesn't celebrate its accomplishments enough. But when you take a step back and look at all of the great things ASHP has done over the years and is still doing to advance healthcare and pharmacy practice, it is not just impressive—it's amazing! Further, and more importantly, the beneficiaries of this leadership and vision are the patients we serve and the health outcomes they achieve by having a pharmacist responsible for their care.

### **Celebrating ASHP members, leaders, and staff**

Just to be clear, when I say ASHP, I mean you. You are ASHP, and you are the ones who make it all happen. For that, please give yourselves a round of applause and reflect for a moment on

the profound impact you have had on improving patients' lives.

I would also like to take a moment to recognize ASHP's exceptional staff of over 200 professionals who live the mission and work tirelessly on behalf of our members and the patients they serve every single day. Please give our staff a round of applause. Also, I would like to welcome two new members of our senior leader team, Gregory Smith, vice president and chief information officer, and Dr. Daniel Cobaugh, assistant vice president and editor in chief of *AJHP*.

Now let's talk about our elected leadership: first, the ASHP Board of Directors. The ASHP membership elects individuals with a vision for the future, a deep respect for ASHP's history of leadership, and an understanding of the broader public health, scientific, and practice advancement roles that ASHP plays. It is a true pleasure for me to have the opportunity to serve as the CEO of ASHP and to work together with the Board to advance patient care. In addition, we are blessed to have our past presidents who continue to tirelessly support us and never stop moving the profession ahead. Let's give the Board and our past presidents a round of applause.

I would now like to take a few minutes to summarize a number of important accomplishments over the past year and to share some of our plans for the future.

### **Pharmacy work force and an evolving healthcare delivery system**

The 2014 National Pharmacist Workforce Survey revealed that 29% of pharmacists practice in hospitals and another 17% practice in patient care settings such as clinics, home infusion, nuclear pharmacy, specialty pharmacy, and long-term care.<sup>1</sup> Based on these numbers, I think it is safe to say that ASHP now represents a very large segment of the pharmacy profession. The outlook is

very positive for patients, given the advanced practices of our members as part of interprofessional teams in hospitals, clinics, and various related practice settings. I believe this growth is something we should all celebrate, not just because ASHP is growing but because the patient-centered pharmacy practice models that ASHP members envisioned 50 years ago are flourishing.

I would now like to touch on evolving healthcare delivery models, and the roles pharmacists play. By now, many are part of accountable care organizations, patient-centered medical homes, and similar healthcare models. The evolution of these new healthcare delivery models and related outcomes and the quality-based payment systems associated with them has provided great new opportunities for pharmacists, especially in hospitals and clinics. ASHP members all over the country are now leading efforts to ensure appropriate prescribing and optimal medication therapy outcomes on interprofessional teams and are driving improvement in key quality measures that link payment with performance. The fundamental changes that are occurring in healthcare are well aligned with the capabilities of ASHP members. I don't think it is an overstatement to say that this may very well become one of the eras of great opportunity to advance the practice of pharmacy, with our patients being the ultimate beneficiaries.

### **Provider status**

In 2014, ASHP and the Patient Access to Pharmacists' Care Coalition were successful in our advocacy to introduce pharmacists' provider status legislation, H.R. 4190.<sup>2</sup> This legislation, which enjoyed great support by both Republicans and Democrats, would amend the Social Security Act to recognize pharmacists as Medicare Part B providers working within their states' scopes of practice in the large number of medically underserved

areas—both urban and rural—throughout the United States.

I am happy to report that this important piece of legislation, now known as H.R. 592—the Pharmacy and Medically Underserved Areas Enhancement Act—was reintroduced in January by Representatives Brett Guthrie, G. K. Butterfield, Todd Young, and Ron Kind.<sup>3</sup> Also in January, Senators Charles Grassley, Mark Kirk, Sherrod Brown, and Robert Casey introduced a companion bill in the Senate, S. 314.<sup>4</sup> At present, we have 136 cosponsors in the House and 16 in the Senate.

Another development that I would like to share with you is that the ASHP Board of Directors recently allocated over \$1 million to help fund a comprehensive provider status media campaign by the Patient Access to Pharmacists' Care Coalition that is aimed at lawmakers and their staff and other policy influencers and stakeholders. With a growing number of supporters of this important legislation, we want to remind everyone just how serious we are and how important it is to increase access to the patient care services of pharmacists. We believe the campaign will be an important tool to do that. This advertising campaign tells the bills' sponsors and potential sponsors in Congress that ASHP and the Coalition are behind them every step of the way. It also lets others know that pharmacists stand ready to help meet the needs of underserved patients in urban and rural areas around the country.

ASHP staff and members have taken a major leadership role in bringing this legislation to fruition and helping advance it through Congress. The fact that ASHP members provide exceptional care as pharmacy generalists and specialists in hospitals, clinics, and other settings has made this effort possible, and it has clearly paid off. These efforts by our members, who we know are already patient care providers, have been

a shining example to Congress of what pharmacists can do to advance healthcare and improve patients' lives. I am absolutely certain that when provider status for pharmacists becomes the law of the land, ASHP members will lead the way in implementing this law.

Regarding outreach and support from other stakeholders, the January 2015 white paper by the National Governors Association expressed strong support for the expanding roles of pharmacists, including recognizing pharmacists as Medicare providers.<sup>5</sup> This report calls on states and Congress to expand the roles pharmacists can and should play in the care of patients and sets the stage for every state in the country to examine its laws and regulations to ensure that pharmacists are able to practice at the top of their license and provide care that improves outcomes and decreases healthcare costs.

However, with all of the great recognition of pharmacists and the progress we have made on provider status, we still have a lot of work to do through 2015. It is absolutely vital that all ASHP members continue to reach out to their members of Congress to express their support and to ask them to cosponsor, or thank them if they are already cosponsoring, this important legislation. Further, we need you to form local coalitions with other patient and healthcare professional groups and colleagues with whom you work to get their support and tell your stories as pharmacists and patient care providers through editorials and op-eds in your local newspapers, blogs, and social media outlets. You can attend political rallies, fundraisers, and other events with your members of Congress to ask them to support the legislation and to talk with them about how this legislation will help patients in your community and state.

It is great to see how some states are leading the charge to expand pharmacists' scope of practice and

to ensure that pharmacists are recognized as providers at the state level. In May of this year, ASHP's affiliate in Washington state was successful in passing legislation that requires Washington's health plans to cover the patient care services provided by pharmacists.<sup>6</sup> This important milestone will prove to be extremely helpful when provider status legislation is passed at the federal level.

I would like to take a moment before I conclude my comments about provider status to talk about the important roles that pharmacy students are playing. At the 2014 Midyear Clinical Meeting, students participated in a standing-room-only ASHP political action committee fundraising session. In February 2015, nearly 75 students came to Washington, D.C., to participate in an ASHP-hosted student legislative day, which included students meeting with their members of Congress to discuss the importance of provider status. Further, students all over the country, who are registered voters, have participated in organized letter-writing campaigns and other political outreach efforts in support of provider status. It is inspiring and exciting to see our students—the future of our profession—taking such an active role in these efforts. Let's take a moment to recognize our student leaders and thank them for their leadership.

### **Ambulatory practice**

A major area of growth in pharmacy practice and ASHP membership is in ambulatory care. The number of residents completing postgraduate year 2 ambulatory care residencies is on the rise, and the most recent Board of Pharmacy Specialties ambulatory care certification program, which ASHP petitioned for, is also growing.

Pharmacists who provide direct patient care services in clinics and other ambulatory care settings are choosing ASHP as their profes-

sional home. ASHP provides a vast amount of resources, educational content, and professional development opportunities for pharmacists practicing in ambulatory care settings across the entire continuum of care. ASHP recently launched the Pharmacy Ambulatory Care Tracker app,<sup>7</sup> which will help pharmacists more effectively track their patient care interventions and document their patient successes. Later this year we will be releasing a free online ambulatory care self-assessment tool that is being built from the recommendations of the 2014 Ambulatory Care Conference and Summit. This tool will help pharmacists determine where they are regarding the provision of ambulatory services and will help them develop a strategic plan to implement and enhance their ambulatory care services.

I believe that a major part of what makes ASHP so attractive to ambulatory care practitioners is our vision for practice, as set forth in the ASHP 2014 Ambulatory Care Conference and Summit.<sup>8</sup> Summit participants envisioned pharmacists being responsible and accountable for medication therapy on every patient care team in every ambulatory care setting. Now, as with every vision, it requires time and effort to fully actualize, and it requires the collective efforts of many. That vision for us includes the need to have many more pharmacists practicing in all clinics and community health centers to improve medication therapy outcomes.

Pharmacy education will need to become increasingly more inter-professional, and pharmacy school curriculums will need to prepare students for new practice roles, such as prescribers and practitioners with enhanced patient assessment skills. ASHP state affiliates will need to work with state legislators to change pharmacy practice acts so that pharmacists can provide the full range of services—including prescribing—that they are

educated, trained, and privileged to provide. I recognize that there are challenges to making things like these happen, but, given their importance and value to patient care, I know that ASHP members, just as they always have, will rise to the occasion. Further, I can promise you that ASHP will support you every step of the way with the best and most effective advocacy, education, products, services, and other resources available.

### **New ASHP brand**

Last year ASHP launched a new logo and tag line. The new tag line, *pharmacists advancing healthcare*, recognizes the broad and expansive roles pharmacists play in healthcare today. The new logo conveys the evolutionary nature of ASHP as a contemporary and innovative organization that is always looking to the future of patient care and pharmacy practice. Further, as the healthcare system continues to evolve in ways that envision higher degrees of connectivity among all patient care settings and greater responsibility of healthcare practitioners and organizations for patient care outcomes across the entire spectrum of care, ASHP has evolved to meet the needs of pharmacy professionals in all care settings.

As you know, health systems today include so much more than a hospital. They include ambulatory care clinics, physician and interprofessional office practices, accountable care organizations, medical homes, and multihospital systems that span multiple states and, in some cases, international lines. Therefore, ASHP members have become less defined by where they practice and more defined by how they practice as direct patient care providers and leaders wherever patients have medications prescribed and administered and where they are seen for follow-up and monitoring.

We hope our new logo and tag line communicate this to pharmacists,

other healthcare professionals, and the public.

### **State leadership and national partnerships**

I would like to take a moment to express my thanks and to recognize the incredible importance of ASHP state affiliates in supporting the ASHP vision, mission, and strategic plan. Our 52 highly effective affiliates work on our behalf to advance pharmacy practice and ASHP's initiatives at the state and local levels. The United States was founded based on the unique traditions and individuality of its 50 states. ASHP state affiliates also exhibit these powerful traditions and characteristics, and these are what make them so effective at understanding the needs of the citizens of their state and of their members. One of the best parts of my job is getting to travel and visit with our affiliates, and my goal is to visit them all. Since the 2014 House of Delegates meeting, I have had the pleasure of visiting affiliates in Arizona; Tennessee; Arkansas; Washington, D.C.; and Iowa. I have now visited a total of 20 states since accepting this position at ASHP. I am extremely thankful for all that our affiliates do and look forward to continuing to work with them to advance ASHP's vision.

In addition to our state affiliates, the partnerships ASHP has forged at the national level over the years have served as vital strategic assets in advancing the ASHP vision and mission. ASHP continues to partner with national organizations such as the American Hospital Association, the Joint Commission, the National Consumers League, the American Nurses Association, the National Rural Health Association, the United States Pharmacopeia, the National Patient Safety Foundation, many physician organizations, the Pew Charitable Trusts, the U.S. Congress, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Centers for Disease

Control and Prevention (CDC), and, of course, all of the national pharmacy organizations. These partnerships reflect the various relationships that ASHP members have when working on the frontlines of patient care and are important to the future and success of ASHP and pharmacists as patient care providers.

Another important partnership that I would like to spotlight is the Pharmacy Technician Accreditation Commission (PTAC). PTAC met for the first time in May, and we are extremely happy to be working with the Accreditation Council for Pharmacy Education (ACPE) on this important initiative. As we all know, pharmacy technicians are critical to the advancement of pharmacy practice and, most importantly, the health and well-being of our patients. PTAC represents a strategic alliance between ASHP and ACPE that recognizes the need to have an educated and well-trained pharmacy technician work force. We are so happy to be working with ACPE on this important effort and believe strongly that advancing pharmacy practice cannot be fully achieved until we enhance the capabilities and practices of the pharmacy technician work force in all settings.

Just before I departed for this meeting, I had the pleasure of participating in the White House Antibiotic Stewardship Forum.<sup>9</sup> The President of the United States has expressed serious concerns about the growing threat of resistant organisms and the general lack of new and emerging antimicrobial therapies to combat them. ASHP was invited to this important event because our members have been the leaders in antimicrobial stewardship for decades, and ASHP has been developing guidelines, education, training, research, and other tools long since then. I am looking forward to continuing to work with the White House and CDC on this important initiative and for ASHP and our

members to play a leading role in identifying and implementing the solutions to this vexing patient safety and public health problem.

### A new era for *AJHP*

As I previously mentioned, Dr. Daniel Cobaugh was named the editor in chief of *AJHP* earlier this year. Daniel comes to *AJHP* after having served in various leadership roles in both ASHP and the ASHP Research and Education Foundation for over a decade and having served in various clinical roles as a practitioner in some of the nation's largest health systems. As you know, *AJHP* has had a long line of renowned editors, including C. Richard Talley, William A. Zellmer, George Provost, and Donald Francke. Dr. Cobaugh stands right there with them as a visionary leader who plans to take a great pharmacy journal to even greater levels. The launch of *AJHP Residents Edition* is just one example, but there is also a planned redesign of the journal that will bring an entirely new face to *AJHP* and incorporate the best of what digital and print media have to offer. Further, plans are underway to enhance the author and reviewer experience and to find novel ways to prepare a new generation of authors to publish their research and practice innovations in *AJHP*. I can tell you now that you are going to be delighted. *AJHP* has always been an exceptional scientific and clinical journal, and I have complete confidence that the new *AJHP* will raise the bar again.

### Conclusion

I believe it is clear that there are many important things going on, and ASHP has big plans for the future. I hope it is also clear that everything ASHP does is for and about our members and the patients they serve. The success of ASHP and its members has always been centered on one thing: the patient. It is this authentic

focus and the genuine desire to improve patient care and overall public health that have made ASHP the highly trusted and respected organization it is today.

Profound change has and will continue to occur in healthcare, but it presents amazing opportunities for pharmacists and ASHP members to take on expanded patient care roles. ASHP has always been and will always be an organization that seeks to transform pharmacy practice so that pharmacists can realize their full potential to improve patient care.

Thank you so much for being here today and for everything you do for your patients and for ASHP.

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pharmacists advancing healthcare

# New Business Item

**AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS  
HOUSE OF DELEGATES  
JUNE 9, 2015  
DENVER, COLORADO**

**INTRODUCED BY (NAME):**

Diane Fox (TX), Julie Nelson (TX), Jim Wilson, (TX), Lance Ray (TX) Patricia Meyer (TX), Lourdes Cuellar, TX, Shane Steven Green (President TSHP), Larry Egle (Immediate-Past President TSHP)

**SUBJECT:**

Controlled Substance Accessibility

**MOTION:**

ASHP should collaborate with other national healthcare organizations, the Drug Enforcement Administration, the National Wholesale Drug Association, the National Association of Chain Drug Stores, and other stakeholders to investigate the inconsistencies in patient access to pain medications and develop strategies to meet legitimate pain care needs for patients.

**BACKGROUND:**

Health System patients have reported extreme difficulty in access to pain medications, especially hydrocodone containing products across the United States. The inability to obtain these necessary medications is resulting in disruption of pain management for patients transitioning from acute care settings to the ambulatory setting. This issue is becoming a major public health problem in the United States. In addition, patients who attempt to find legitimately prescribed pain therapy have been labeled "drug seekers" and are prevented from obtaining these medications at local drug stores. Health System pharmacies have begun filling outpatient pain medication prescriptions for their patients which has jeopardized the availability of pain therapy for inpatients due to allocations and medication shortages. ASHP policy 1106 - Statement of Pain Management supports appropriate pain manage strategies and as such; ASHP should take the lead in increasing the access to pain medications for legitimate pain therapy. Identifying the factors contributing to decreased access and working to resolve them is a health care priority for the benefit of our patients.

**SUGGESTED OUTCOMES:**

1. ASHP should aggressively work with other interested parties, such as health system pharmacies, health care organizations, wholesalers, chain drugs stores, and the Drug Enforcement Administration to determine why these medications are not accessible and to patients with legitimate health care needs and develop plans to resolve the inaccessibility problem.
2. ASHP should develop a repository of specific patient experiences to use in telling the story.
3. ASHP should advocate for changing ALL policies that result in inaccessibility to legitimate pain management therapy for patients.

# ASHP Board of Directors, 2015–2016

Am J Health-Syst Pharm. 2015; 72:e48



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 ASHP REPORTS
 

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*Inaugural address of the Incoming President*

# Building bridges to pharmacy's future: Optimizing patient outcomes

JOHN A. ARMITSTEAD

Am J Health-Syst Pharm. 2015; 72:1403-6

To say it is an honor to serve as your president is an understatement. I am so grateful for this opportunity to serve our patients, our profession, and our society.

Ever since my introduction to ASHP during my college years at Ohio Northern and my ongoing training at Ohio State, I have been intrigued and invigorated by this great professional society. Its influence on my career has been remarkable. ASHP has opened my heart and mind to opportunity and action. The examples set by many of our profession's finest leaders have created pathways and bridges to grow professionally and realize dreams.

I have many individuals to thank, starting with my wife, life partner and best friend—also a pharmacist—Ima Darling Armitstead. Thank you for your love, support, and guidance. You have given me infinite refills on our prescription for life.

I want to thank my children, Jaclyn and Jonathan; my parents, Austin and Bianca; my sister Nancy; my brother Alan; and my parents-in-love, Frank and Pat. My inner circle of love also includes Armitsteads,

*Pharmacy practice is synonymous with bridge building. Today, we have new opportunities to step into ambulatory and primary care settings, working on healthcare teams in accountable care organizations, physician's offices, hospital outpatient clinics and pharmacies, patient-centered medical homes, and community healthcare centers.*



Haydens, and, of course, the Darling sisters. The support of my family, from birth and through marriage, from student to practitioner and leader, has been a bedrock of joy for me.

As I was considering what I wanted to speak about today, I discovered an insightful poem by Will Allen Dromgoole<sup>1</sup> called "The Bridge Builder." In it, an elderly man crosses a lazy stream and then turns around to construct a bridge to provide others with safe passage. The man is asked why he built a bridge when he

had already safely crossed the wide chasm:

*The builder lifted his old gray head;  
'Good friend, in the path I have come,'  
he said,  
'There followed after me to-day  
A youth whose feet must pass this way  
That chasm that has been as naught  
to me  
To that fair-haired youth may a pitfall  
be;  
He, too, must cross in the twilight dim;  
Good friend, I am building the bridge  
for him!'*

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Presented at the ASHP Summer Meetings, Denver, CO, June 9, 2015.

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As I reflect on the profession of pharmacy, specifically pharmacy in health systems, I am thankful for the past leaders—bridge builders for all of us—who had a vision, sought consensus, and made the act of patient care delivered by pharmacists what it is today.

These leaders have advanced our profession and patient care by publishing, presenting, and developing practice guidelines and policies. They have advocated for pharmacy and for patients. They have precepted, networked, and mentored the next generation. They have built the bridges that we easily cross today.

In my career of 35 years, many bridge builders have paved the way for me. I especially want to thank Marianne Ivey, Clifton Latiolais, Thomas Sherrin, Paul Parker, Mick Hunt, Philip Schneider, Janet Silvester, Kevin Colgan, Henri Manasse, Paul Abramowitz, William Zellmer, Fred Eckel, Steven Rough, Kelly Smith, Christene Jolowsky, Clifford Hynniman, Thomas Theilke, Daniel Ashby, Herman Lazarus, Sara White, Harold Godwin, Roger Anderson, David Zilz, and my Florida colleagues and dear friends, James McAllister and Robert Rapp.

Thanks also to my colleagues throughout the years at some of the nation's finest healthcare institutions, including the U.S. Public Health Service, Riverside Methodist Hospitals, Ohio State University Hospitals, University of Cincinnati Hospital, University of Kentucky Healthcare, and my current team at Lee Memorial Health System. These institutions and their staff have allowed me to apprentice and engineer improved patient care outcomes.

### **Bridges for our patients**

When I was a child living in New York City, I watched the building of the Verrazano-Narrows Bridge connecting Staten Island to Brooklyn. Before the bridge was built, you could only cross the choppy waters

of the Hudson River by ferry. There was a gap called “the Narrows”—the gateway to New York Harbor—a chasm of two miles created 18,000 years ago at the end of the Ice Age. When the Verrazano was completed in 1964, it connected these lands to development, commerce, expansion, and growth. The chasm was bridged.

Today, I want to talk to you about the importance of bridging the gaps in continuity of care, in our relationships with patients and peers, and in the work that ASHP is doing every day to further our professional aspirations and goals.

We have come so far on the road to improved patient outcomes and enhanced opportunities for pharmacists as key members of the health-care team. We must continue to build bridges for patients in transitions of care and in ambulatory care. We must forge ahead and continue to redefine our profession, strengthen our work force, and nurture and maintain our relationships and connections.

Great examples abound of how pharmacists are moving into direct patient care in ambulatory care settings. At Avera Behavioral Health Center in Sioux Falls, South Dakota, pharmacists have transitioned to clinical services and patient-specific care by focusing on medication reconciliation, patient education, and targeted medication therapy protocols and by managing drug-induced adverse effects in their mental health patients.

At Palomar Health in Escondido, California, pharmacists are working throughout the continuum of care by developing an effective transitions-of-care program that emphasizes medication safety and individual patient outcomes. They accomplish this through a community-based transitions program.

Effective transitions from hospital to home or from a community setting into the hospital are key areas in which pharmacists can make a differ-

ence. Pharmacists can bring value in both guarding against newly emerging medication-related problems and the potential for an escalation of adverse conditions as patients transition to home settings.

Care transitions with a focus on medication management are essential to improve health outcomes. The distinct medication expert on the multidisciplinary team is the pharmacist. In concert with physicians, nurses, and others who contribute to the overall care of patients, pharmacists can develop care plans that translate into reduced readmissions and improved outcomes.

Results of ASHP's most recent national survey revealed that practice is evolving and that pharmacists are becoming more and more involved in transitions of care.<sup>2</sup> Over 60% of responding health systems task pharmacists or pharmacy technicians with taking medication histories at admission, and over 60% have pharmacists conduct discharge medication counseling and discharge planning.

Although progress has been made, pharmacists must do better, and we must do it much quicker. Incremental change will no longer suffice.

We need to take responsibility for our patients' medication education and their ongoing care. We must begin to care about the whole life of the patient rather than just the episodic care we provide at different points in the care process. It is time to accelerate our incremental efforts into monumental success for our patients.

We must ensure continuity of care during patient transitions between care settings, and we must manage care effectively.

We must be the key provider who follows up on drug-related problems, and we must effectively conduct medication education to promote patient self-care.

Let me give you a personal example of what I'm talking about. Recently, I had a patient who had

gone home after surgery and was prescribed an analgesic. Because my contact information is included on the discharge patient education information, the patient called me.

His question was not something related to pain control or medication interactions. He wanted to know why he hadn't had a bowel movement in over three days. Now, that may seem like a low-level concern for a pharmacist with years of clinical experience and training, but, for this patient, constipation was the driving concern. His issue was resolved after daily consultation with his pharmacist—three, four, and five days after discharge.

If you are wondering if something this mundane is important to the whole life of your patient, I'm here to say emphatically, yes. We have to be ready to manage everything related to our patients' medication regimens beyond their hospitalization.

### **Bridges to ambulatory care and primary care**

As you can see, bridges are not simply a metaphor to me. They are connections that link one place to another. They stand as a testament to our ingenuity. This pharmacist-to-be was born and raised in New York City, and there certainly is no more iconic bridge than the Brooklyn Bridge. Completed in 1883, it is truly a magnificent feat of engineering, a wonder of the world. It stands strong today.

Pharmacy practice is synonymous with bridge building. Today, we have new opportunities to step into ambulatory and primary care settings, working on healthcare teams in accountable care organizations, physician's offices, hospital outpatient clinics and pharmacies, patient-centered medical homes, and community healthcare centers.

Indeed, one of the most exciting recent developments has been the increasing number of pharmacists who are becoming part of patients' medi-

cal homes. Patients are welcoming us into that space because of our critical role in medication therapy management to optimize outcomes.

As electronic medical records continue to advance, they will eventually become patient owned and held. Once that happens, I believe patients will see clearly what an essential role we play, and patients will have their own pharmacists.

It is truly an exciting time! We can find examples everywhere of how far pharmacist care has come.

Pharmacists at Kimbrough Ambulatory Care System in Fort Meade, Maryland, are providing primary care services to military veterans. Pharmacists manage patients' lipids and anticoagulation and assist with postdeployment care of soldiers. Kimbrough pharmacists are building bridges of care for our military heroes and their families.

The diabetes medical management clinic in the Department of Veterans Affairs San Diego Healthcare System is run by pharmacists and provides integrated care that covers not only diabetes but hypertension, lipids, food choices, activity, adherence, and motivation. These pharmacists are helping patients improve their personal goals. They are bridging the care gaps and changing lives as a result.

In both ambulatory and primary care settings, pharmacists are accomplishing great things. But we need to continue to push for progress in this area, particularly on the issue of provider status for pharmacists. We all must support ASHP's assertive advocacy in Congress and reach out to our own senators and representatives to make sure they know that pharmacists can improve patient care.

We must achieve provider status recognition for pharmacists' critical role in ambulatory care, primary care, immunizations, and medication therapy management. And we must create the kinds of sustainable business models that ensure pharmacists

are compensated for their expertise and training.

### **Bridges to interdisciplinary care**

We are now carving out our essential roles in patients' lives as well as our place in patient-centered medical homes. But we need to build more bridges to interdisciplinary care. Team-based care will require patients to actively participate in their own health and wellness through disease prevention, treatment, and monitoring to ensure the best outcomes.

Ladies and gentlemen, you cannot build a bridge without architects, engineers, builders, and inspectors. Likewise, patient care cannot be effectively rendered without physicians, nurses, pharmacists, and care management—the entire allied health team.

Consider the work of the health-care team at the Mountain Area Health Education Center in Asheville, North Carolina, where pharmacists manage specialty clinics in anticoagulation, osteoporosis, and care transitions. Multidisciplinary teams collaborate, and pharmacists expertly manage drug selection, titration, and monitoring. Interdisciplinary care and optimal patient outcomes are the drivers for everything this team does.

### **Bridges within our profession**

The aforementioned example raises the obvious question: How can we inspire our future leaders to provide this kind of care? How can we energize accomplished clinicians with new insights? And what must we do to equip our successors so that they can become leaders, coaches, teachers, motivators, and strategists?

We must clear out any barriers that block both their individual growth and our progress as a profession. Every pharmacist must be prepared to lead.

It is clear to me that simply relying on a pharmacy education that is years behind us and investing only in modest continuing-education efforts

will not be enough to help us become optimal patient care providers.

As a strong supporter of continuous professional development (CPD) for all members of our work force—pharmacists and pharmacy technicians—I believe each individual must play an engineer’s role in the construction of new bridges to our future.

CPD is the means by which people maintain, develop, and advance their professional skills and knowledge. It is a structured approach to learning that helps ensure the advancement of competencies to practice, taking in new knowledge, skills, and practical experience. CPD is a way to practice at the top of your license.

At my institution, I ask that every pharmacist and pharmacy technician develop his or her own CPD plan. Individuals are encouraged to stretch beyond their reach to develop skills for future practice.

This includes innovations related to practice advancements, lean transformation activities, practice-related competencies, specialty certifications, preceptor development, and teaching certificates. These activities are designed to enhance the training, competency, and performance of every pharmacist and technician.

Lee Memorial’s support and encouragement of CPD plans are

helping to enhance pharmacists’ and pharmacy technicians’ contributions to patient care and are propelling our profession forward.

As a guide for your individual CPD plan, I am reminded of this quote by Arthur Ashe<sup>3</sup>: “Start where you are. Use what you have. Do what you can.”

### **Bridges we must build**

The message I want to leave you with today is that it is time for all of us to build bridges to the future, connections that will allow us to take on new roles that will benefit our patients.

It is time for full utilization of pharmacist skills as the medication therapy expert.

It is time to create seamless delivery of care to our patients.

Pharmacists and pharmacy technicians are poised to optimize patient outcomes through interdisciplinary medication management. I hope you’ll keep the following in mind as we all work to advance the care of patients:

1. We must improve the continuity of care for every patient through advancing pharmacists’ role in ambulatory and primary care.
2. We must become team-based, collaborative care leaders.

3. We must achieve provider status for pharmacists.
4. We must individually dedicate ourselves to robust CPD.

If you were to ask me to pick the most important of these four, it would be CPD. CPD will help us to maintain practice excellence, will enhance the chances for achieving provider status, and will elevate pharmacists’ role as patient care providers.

In closing, I will recast a portion of the poem “The Bridge Builder” that I mentioned at the start of today’s remarks:

To our patients may a pitfall be.  
They, too, must cross in the twilight dim;  
Good friend, pharmacists are  
building the bridge for them.

Let’s build those bridges!

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# Professional Policies Approved by the 2015 ASHP House of Delegates

DENVER, CO  
JUNE 9, 2015

*Am J Health-Syst Pharm.* 2015; 72:e49-54

The new professional policies approved by the ASHP House of Delegates at its June 2015 session are listed below. Policies proposed by councils or other ASHP bodies are first considered by the Board of Directors and then acted on by the House of Delegates, which is the ultimate authority for ASHP positions on professional issues.

The background information on these policies appears on the ASHP Web site ([www.ashp.org](http://www.ashp.org)); click on “Practice and Policy” then on “House of Delegates,” and then on “Board of Directors Reports on Councils” (<http://www.ashp.org/DocLibrary/Policy/HOD/CouncilReports.aspx>).

The complete proceedings of the House of Delegates will be provided to delegates and will be posted on the ASHP Web site.

## 1501

### Pharmacist Participation in Health Policy Development

*Source: Council on Public Policy*

To advocate that pharmacists participate with policymakers and stakeholders in the development of health-related policies at the national, state, and community levels; further,

To develop tools and resources to assist pharmacists in fully participating in health policy development at all levels.

## 1502

### Pharmacist Recognition as a Healthcare Provider

*Source: Council on Public Policy*

To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as healthcare providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as healthcare providers, improve access to patient care and bridge existing gaps in healthcare; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

To advocate for sustainable compensation and standardized billing processes used by payers for pharmacist services by all available payment programs.

*This policy supersedes ASHP policy 1307.*

## 1503

### Pharmaceutical Product and Supply Chain Integrity

*Source: Council on Public Policy*

To encourage the Food and Drug Administration (FDA) and relevant

state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate for improved transparency so that drug product labeling include a readily available means to retrieve the name and location of the facility that manufac-

tured the specific lot of the product; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product and its raw materials; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

*This policy supersedes ASHP policy 0907.*

#### 1504

##### **Patient Adherence Programs as Part of Health Insurance Coverage**

*Source: Council on Public Policy*

To advocate for the pharmacist's role in patient medication adherence programs that are part of health insurance plans; further,

To advocate those programs that (1) maintain the direct patient pharmacist relationship; (2) are based on the pharmacist's knowledge of the patient's medical history, indication for the prescribed medication, and expected therapeutic outcome; (3) use a communication method desired by the patient; (4) are consistent with federal and state regulations for patient confidentiality; and (5) permit dispensing of partial fills or overfills of prescription medications in order to synchronize medication refills and aid in medication adherence.

*This policy supersedes ASHP policy 0116.*

#### 1505

##### **Statutory Protection for Medication-Error Reporting**

*Source: Council on Public Policy*

To collaborate with other health-care providers, professions, and stakeholders to advocate and support state and federal legislative and regulatory initiatives that provide liability protection for the reporting of actual

and potential medication errors by individuals and healthcare providers; further,

To provide education on the role that patient safety organizations play in liability protection.

*This policy supersedes ASHP policy 0011.*

#### 1506

##### **Premarketing Comparative Clinical Studies**

*Source: Council on Public Policy*

To advocate that the Food and Drug Administration have the authority to impose a requirement for comparative clinical trials.

*This policy supersedes ASHP policy 0514.*

#### 1507

##### **Funding, Expertise, and Oversight of State Boards of Pharmacy**

*Source: Council on Public Policy*

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

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

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

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

*This policy supersedes ASHP policy 0518.*

#### 1508

##### **Support for FDA Expanded Access (Compassionate Use) Program**

*Source: Council on Public Policy*

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the sole mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to such drugs under the FDA Expanded Access Program; further,

To advocate that IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol.

#### 1509

##### **Approval of 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 interchange-

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

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

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

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

*This policy supersedes ASHP policy 1409.*

## 1510

### Naloxone Availability

*Source: Council on Therapeutics*

To recognize the potential public health benefits of naloxone for opioid reversal; further,

To support efforts to safely expand access to naloxone; further,

To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone after receiving education; further,

To foster education on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care; further,

To support state efforts to authorize pharmacists' prescribing authority for naloxone for opioid reversal.

## 1511

### Complementary and Alternative Medicine in Patient Care

*Source: Council on Therapeutics*

To promote awareness of the impacts of complementary and alternative (CAM) products on patient care, particularly drug interactions, medication safety concerns, and the risk of contamination and variability in active ingredient content; further,

To advocate for the documentation of CAM products in the health record to improve patient safety; further,

To advocate for the inclusion of information about CAM products and their characteristics in medication-related databases; further,

To provide education on the impacts of CAM products on patient care in healthcare organizations; further,

To foster the development of up-to-date and readily available resources about CAM products.

## 1512

### Development of Abuse-Resistant Narcotics

*Source: Council on Therapeutics*

To advocate that the Food and Drug Administration investigate the efficacy of abuse-resistant formulations in preventing prescription drug abuse.

## 1513

### Quality Patient Medication Information

*Source: Council on Therapeutics*

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, and simplicity of written patient medication information (PMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level, for PMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of PMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly accessible central repository of PMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of PMI.

*This policy supersedes ASHP policy 1012.*

## 1514

### Safety and Effectiveness of Ethanol Treatment for Alcohol Withdrawal Syndrome

*Source: Council on Therapeutics*

To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to treat AWS; further,

To educate clinicians about the availability of alternative therapies for AWS.

*This policy supersedes ASHP policy 1010.*

## 1515

### Research on Drug Use in Obese Patients

*Source: Council on Therapeutics*

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in obese patients to facilitate safe and effective dosing of medications in this patient population, especially for medications most likely to be affected by obesity; further,

To encourage manufacturers to include in the Food and Drug Administration (FDA)–approved labeling detailed information on characteristics of individuals enrolled in drug dosing studies; further,

To advocate that the FDA develop guidance for the design and reporting of studies that support dosing recommendations in obese patients; further,

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

To encourage independent research on the clinical significance of obesity on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms.

*This policy supersedes ASHP policy 1013.*

## 1516

### Chemotherapy Parity

*Source: Council on Therapeutics*

To advocate that all insurance

payers design plans so that patient cost sharing for chemotherapy be equivalent regardless of route of administration; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of chemotherapy agents regardless of route of administration.

## 1517

### Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship

*Source: Council on Therapeutics*

To advocate involvement of pharmacists in the clarification of penicillin allergy, intolerance, and adverse drug events; further,

To advocate for documentation of penicillin allergy, intolerance, reactions, and severity in the medical record to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing in appropriate candidates when clinically indicated to optimize antimicrobial selection.

## 1518

### Developing Leadership Competencies

*Source: Council on Education and Workforce Development*

To work with healthcare organization leadership to foster opportunities for pharmacy practitioners to move into leadership roles; further,

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

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

To encourage colleges of pharmacy and ASHP state affiliates to collaborate in fostering student leadership skills through develop-

ment of co-curricular leadership opportunities, leadership conferences, and other leadership promotion programs; further,

To reaffirm that residency programs should develop leadership skills through mentoring, training, and leadership opportunities; further,

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

*This policy supersedes ASHP policy 0509.*

## 1519

### Pharmacy Technician Training and Certification

*Source: Council on Education and Workforce Development*

To support the position that by the year 2020, the completion of a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required to obtain Pharmacy Technician Certification Board certification for all new pharmacy technicians entering the workforce; further,

To foster expansion of ASHP-ACPE accredited pharmacy technician training programs.

*This policy supersedes ASHP policies 1015 and 0702.*

## 1520

### Impact of Insurance Coverage Design on Patient Care Decision

*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 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 1017.*

## 1521

### Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs

*Source: Council on Pharmacy Management*

To advocate that pharmacists or pharmacy technicians ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist-patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist-patient relationship.

*This policy supersedes ASHP policy 0603.*

## 1522

### Disposition of Illicit Substances

*Source: Council on Pharmacy Management*

To advocate that healthcare organizations be required to develop procedures for the disposition of illicit substances brought into a facility that ensure compliance with applicable laws and accreditation standards; further,

To advocate that healthcare organizations be required to include

pharmacy leaders in formulating such procedures.

## 1523

### Pharmacist's Role in Population Health Management

*Source: Council on Pharmacy Management*

To recognize the importance of medication management in patient-care outcomes and the vital role of pharmacists in population health management; further,

To encourage healthcare organizations to engage pharmacists and pharmacy leaders in identifying appropriate patient cohorts, anticipating their healthcare needs, and implementing the models of care that optimize outcomes for patients and the healthcare organization; further,

To encourage the development of complexity index tools and resources to support the identification of high-risk, high-cost, and other patient cohorts to facilitate patient-care provider panel determinations and workload balancing; further,

To promote collaboration among members of the interprofessional healthcare team to develop meaningful measures of individual patient and population care outcomes; further,

To advocate for education to prepare pharmacists for their role in population health management.

## 1524

### Support for Second Victims

*Source: Council on Pharmacy Practice*

To acknowledge that the patient is the primary victim in any medical error, unanticipated adverse patient event, or patient-related injury; further,

To acknowledge that involvement by healthcare personnel in such events may cause them to become second victims; further,

To recognize that a just culture and a healthy culture of safety embrace a support system for second victims; further,

To encourage healthcare organizations to establish programs to support second victims; further,

To educate healthcare professionals (including those in training), health organization administrators, and regulatory agencies about the second-victim effect and available resources.

## 1525

### Standardization of Doses

*Source: Council on Pharmacy Practice*

To recognize that standardization of medication doses reduces medication errors and improves information technology interoperability, operational efficiency, and transitions of care; further,

To encourage development of universal standardized doses for specific patient populations; further,

To encourage healthcare organizations to adopt standardized doses and to promote publication and education about best practices.

## 1526

### Prescription Drug Abuse

*Source: Council on Pharmacy Practice*

To affirm that pharmacists have leadership roles in recognition, prevention, and treatment of prescription drug abuse; further,

To promote education on prescription drug abuse, misuse, and diversion-prevention strategies.

## 1527

### Pharmacist's Role in Urgent and Emergency Situations

*Source: Council on Pharmacy Practice*

To affirm that pharmacists should participate in planning and providing emergency treatment team services; further,

To advocate that pharmacists participate in decision-making about the medications and supplies used in medical emergencies; further,

To advocate that pharmacists serve in all emergency responses,

and that those pharmacists receive appropriate training and maintain appropriate certifications.

1528

**Excipients in Drug Products**

*Source: Council on Pharmacy Practice*

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

*This policy supersedes ASHP policy 0808.*

1529

**Online Pharmacy and Internet Prescribing**

*Source: Council on Pharmacy Practice*

To support efforts to regulate prescribing and dispensing of medications via the Internet; further,

To support legislation or regulation that requires online pharmacies to list the states in which the pharmacy and pharmacists are licensed, and, if prescribing services are offered, requires that the sites (1) ensure that a legitimate patient-prescriber relationship exists (consistent with professional practice standards) and (2) list the states in which the prescribers are licensed; further,

To support mandatory accreditation of online pharmacies by the National Association of Boards of

Pharmacy Verified Internet Pharmacy Practice Sites or Veterinary-Verified Internet Pharmacy Practice Sites; further,

To support appropriate consumer education about the risks and benefits of using online pharmacies; further,

To support the principle that any medication distribution or drug therapy management system must provide timely access to, and interaction with, appropriate professional pharmacist patient-care services.

*This policy supersedes ASHP policy 0523.*

1530

**Standardization of Small-Bore Connectors To Avoid Wrong-Route Errors**

*Source: Council on Pharmacy Practice*

To support the use of medication administration device connectors and fittings that are designed to prevent misconnections and wrong-route errors; further,

To encourage healthcare organizations to prepare for safe transition to use of medication delivery device connectors and adapters that meet International Organization for Standardization standards; further,

To identify and promote the implementation of best practices for preventing wrong-route errors.

*This policy supersedes ASHP policy 1018.*

1531

**Pharmacist Role in Capital Punishment**

*Source: Council on Pharmacy Practice*

To acknowledge that an individual's opinion about capital punishment is a personal moral decision; further,

To oppose pharmacist participation in capital punishment; further,

To reaffirm that pharmacists have a right to decline to participate in capital punishment without retribution.

*This policy supersedes ASHP policy 8410.*

1532

**ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive**

*Source: Council on Pharmacy Management*

To approve the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive.\*

1533

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

*Source: Council on Pharmacy Practice*

To approve the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance.\*

1534

**ASHP Statement on the Pharmacist's Role in Clinical Informatics**

*Source: Section of Pharmacy Informatics and Technology*

To approve the ASHP Statement on the Pharmacist's Role in Clinical Informatics.\*

\*The ASHP statements approved by the House of Delegates are available on the ASHP Web site ([www.ashp.org](http://www.ashp.org)). Under "Practice and Policy," click on "Policy Positions & Guidelines" and then on "New Guidance Documents."

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# House of Delegates

## REPORT ON IMPLEMENTATION OF 2014

### ASHP HOUSE OF DELEGATES ACTIONS AND RECOMMENDATIONS

#### **Council on Pharmacy Practice A (1401): Standardization of Oral Liquid Medication Concentrations**

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP is working with FDA to pursue funding for several standardization projects. As part of that process ASHP is developing a white paper for submission to the FDA. ASHP is also partnering with Solutions for Patient Safety (a nationwide network of 80 children's hospitals) to create an expert panel to explore the details of standardization and implementation of standard concentrations of compounded liquid medications.

#### **Council on Pharmacy Practice B (1402): Safe Use of Radiopharmaceuticals**

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

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

To advocate for incorporation of information on radiopharmaceuticals into college of pharmacy curricula and increased pharmacy continuing education on radiopharmaceuticals.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP offered an educational session, Radiopharmaceuticals in Health Systems: Your Role and Responsibilities, at the 2014 Midyear and converted that session into an [e-learning product](#).

#### **Council on Pharmacy Practice C (1403): Pharmacist's Role on Ethics Committees**

To advocate that pharmacists should be included as members of hospital and health-system ethics committees; further,

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to offer the Joseph A. Oddis Ethics Colloquium at ASHP meetings and seeks other opportunities to provide education on the topic.

**Council on Pharmacy Practice D (1404): Safe Use of Fentanyl Transdermal System Patches**

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

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

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 E (1405): Automatic Stop Orders**

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP has advocated directly with CMS to change the conditions of participation regarding automatic stop orders and is working with other interested organizations to achieve this goal.

**Council on Public Policy A (1406): Federal and State Regulation of Compounding**

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

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

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP has been active in [advocating](#) with FDA regarding implementation of the Drug Quality and Security Act (DQSA), which contains provisions concerning FDA registration and current good manufacturing practices requirements for outsourcing facilities as well as adherence to USP Chapter 797 and 795 standards for compounding pharmacies. ASHP continues to advocate with Congress, the FDA, and in individual states on these issues.

**Council on Public Policy B (1407): 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 for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

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

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP offers education about 340B program management at all its meetings, from the daylong workshop 340B University at the [Midyear](#) and [Leadership Conference](#) to shorter, more focused sessions at the [Summer Meetings](#). ASHP continues to advocate with Congress and federal agencies regarding ways to strengthen the 340B program. ASHP was active in educating members and advocating with the Health Services and Resources Administration (HRSA) regarding the 340B Drug Pricing Program's guidance on program changes by the Affordable Care Act including but not limited to the use of [orphan drugs](#) and eligibility by certain hospitals such as critical access, free-standing cancer hospitals, and rural referral centers.

#### **Council on Public Policy C (1408): State Prescription Drug Monitoring Programs**

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

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

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

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP continues to educate Congress and state legislators about the design and implementation of these programs.

#### **Council on Public Policy D (1409): Approval of Biosimilar Medications**

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

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

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

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

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

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

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. An amended version of this policy is before the House for consideration at this session. It was amended to address state legislation regarding substitution of interchangeable biosimilars. In its advocacy with Congress and the FDA, ASHP has supported the biosimilar development pathway, under which the first biosimilar is expected in 2015.

#### **Council on Therapeutics A (1410): Access to Oral Contraceptives Through an Intermediate Category of Drug Products**

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

To support expanded access to these products through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications; further,

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP is revising several [ASHP statements](#) related to a proposed intermediate category of drug products that would be available from all pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications. This policy position continues to be used with those statements, as opportunity allows, to advocate for such a category of drug products and to oppose nonprescription access to oral contraceptives.

#### **Council on Therapeutics B (1411): Expedited Pathways for FDA Drug Approval**

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

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP will continue to use this policy in its advocacy efforts with Congress regarding 21st Century Cures legislation.

#### **Council on Therapeutics C (1412): FDA Oversight of Laboratory-Developed Tests**

To advocate that the Food and Drug Administration be granted increased authority to regulate laboratory-developed tests as medical devices, including tests used for pharmacogenetic testing; further,  
To support development of a risk-based framework for regulatory oversight of laboratory-developed tests that promotes innovation while providing a mechanism to ensure that test results are reliable, reproducible, and clinically relevant; further,  
To encourage expanded availability of commercially marketed pharmacogenetic tests that would be available for use by laboratory and health care professionals to guide drug therapy.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP will continue to use this policy in its advocacy efforts with Congress regarding 21st Century Cures legislation.

#### **Council on Therapeutics D (1413): Ensuring Effectiveness, Safety, and Access to Orphan Drug Products**

To encourage continued research on and development of orphan drug products; further,  
To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,  
To encourage postmarketing research to support the safe and effective use of these drug products for approved and off-label indications; further,  
To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan 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. ASHP was active in educating members and advocating with the Health Services and Resources Administration (HRSA) regarding the 340B Drug Pricing Program's [orphan drug exclusion](#), and ASHP will continue to use this policy in its advocacy efforts with Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA).

#### **Council on Education and Workforce Development A (1414): Cultural Competency and Cultural Diversity**

To promote the development of cultural competency of pharmacy educators, practitioners, residents, students, and technicians; further,  
To educate providers on the importance of providing culturally congruent care to achieve quality care and patient engagement; further,  
To foster awareness of the impact that an ethnically and culturally diverse workforce has on improving health care quality.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. Cultural competence figures prominently in the September 2014 revised [Required Competency Areas, Goals, and Objectives For Postgraduate Year One \(PGY1\) Pharmacy Residencies](#) and is incorporated in many ASHP patient-care related publications and products.

#### **Council on Education and Workforce Development B (1415): Credentialing, Privileging, and Competency Assessment**

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. As an institutional supporter of the Council on Credentialing in Pharmacy (CCP), ASHP has helped communicate CCP's guidance on the topic to pharmacists and healthcare organization administrators. ASHP offers an [online resource center for credentialing and privileging](#), and related educational sessions will continue to be offered at ASHP meetings.

#### **Council on Pharmacy Management A (1416): Pharmacy Department Business Partnerships**

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP has updated the ASHP Statement on the Role of the Pharmacy Executive (a revised version of the statement is being considered by this session of the House) to provide a tool for pharmacy leaders to help educate healthcare organization administrators about these important issues. ASHP continues to provide a variety of tools to empower pharmacy leaders address these challenges, from an [online resource center](#) to [webinars](#) to up-to-the-minute sessions at the annual [Leadership Conference](#).

#### **Council on Pharmacy Management B (1417): Integration of Pharmacy Services in Multifacility Health Systems**

To advocate that pharmacists are responsible for organizational efforts to standardize and integrate pharmacy services throughout the entire pharmacy enterprise in multifacility health systems and integrated delivery networks; further,  
To educate health-system administrators about the importance of pharmacy leadership in setting system-wide policy regarding the safe and effective use of medications; further,  
To advocate for the regulations and resources needed to support efforts to achieve optimal patient health outcomes in multifacility organizations.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP has organized a group of pharmacy leaders from multifacility health systems to identify and addresses their needs in the emerging healthcare environment, and will continue to host networking sessions for that group at ASHP meetings.

#### **Council on Pharmacy Management C (1418): Risk Assessment of Health Information Technology**

To urge hospitals and health systems to directly involve departments of pharmacy in performing appropriate risk assessment before new health information technology (HIT) is implemented or existing HIT is upgraded, and as part of the continuous evaluation of current HIT performance; further,  
To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,  
To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes; further,  
To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts. ASHP has developed guidelines for use of clinical decision support to use as a tool to help educate vendors regarding pharmacy perspectives on HIT that can improve patient-care outcomes.

#### **Council on Pharmacy Management D (1419): Documentation of Patient-Care Services in the Permanent Health Record**

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

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

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 E (1420): Manufacturer-Sponsored Patient-Assistance Programs**

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

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

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

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

This policy has been published in *ASHP Best Practices* (print and online editions) and used in ongoing ASHP advocacy, education, and communication efforts.

#### **Medication Safety Certification (Recommendation): Dan Degnan (IN)**

That ASHP continue to work with the National Patient Safety Foundation (NPSF), the Institute for Safe Medication Practices (ISMP), and other stakeholders to establish a certification process for medication safety professionals.

ASHP worked with the NPSF and the ISMP to assess the feasibility of a certification process for a medication safety credential, conducting a survey to determine interest and need. The organizations determined that the level of interest would not support development of the certification (task analysis, establishment of domains, test development, psychometrics, etc.) at this time, but the organizations agreed to reassess in the near future.

#### **Revision of ASHP Policy 0610, Pharmacist's Right of Conscience and Patients' Right of Access to Therapy: (Recommendation) Nicole Allcock (MO)**

That ASHP revise this policy to better support pharmacists not wishing to cooperate with ethically troubling therapies and change the phrase "provide a referral" to "transfer care."

The Council on Pharmacy Practice considered this recommendation as part of sunset review of existing ASHP policies. The Council and Board found the policy to still be appropriate.

#### **Transparency of Manufacturing Source for Medications (Recommendation): Erin Fox (UT)**

That ASHP advocate that the product labeling for medications disclose both the manufacturer and the location of manufacture.

The Council on Public Policy reviewed this recommendation at its September meeting and recommended amending ASHP policy 0907, Pharmaceutical Product and Supply Chain Integrity, to address this supply chain issue.

**Removal of Section 7.1 from the Bylaws and Placement into an Appendix or Policy (Recommendation): Brian I. Kawahara (CA)**

That ASHP consider removing Section 7.1 of Article 7 of the Bylaws and placing them in an appendix to the Bylaws or a procedural policy.

ASHP staff considered the recommendation and concluded that this could be done when the Bylaws are next updated.

**Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs (Recommendation): Wes Pitts (MS), Laurie Warrington (MS), Stephen Eckel (NC), Dennis Williams (NC)**

That ASHP develop standardized mechanisms and advocacy to identify and document patients' existing prescription drug coverage and to develop triggers to identify patients for PAPs to optimize care transitions.

The Council on Pharmacy Management considered the recommendation at its September meeting and developed a policy recommendation.

**Education About Patient Safety in the Medication-Use Process (Recommendation): Elizabeth Wade (NH), John Hertig (IN), Dan Degnan (IN)**

That ASHP create a task force to assess and develop a guidance document articulating medication safety-related educational needs for pharmacy schools; further, to link the core competencies for the medication safety officer role to the pharmacy curriculum and postgraduate training opportunities.

The Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report.

**Safe Use of Drug-Containing Devices and Diagnostic Agents (Recommendation): Carol Rollins (AZ, ID)**

That ASHP affirm that drug-containing devices and diagnostic agents require standards for safe use and monitoring considerations that involve pharmacy issues; further, to advocate that pharmacy departments, in cooperation with other pertinent departments, are involved in decisions related to the safe use of drug-containing devices and diagnostic agents.

ASHP staff considered this recommendation for a council agenda and concluded that ASHP policy 1313, Drug-Containing Devices, addresses ASHP policy needs for the topic.

**Inclusion of Small, Specialty, Critical Care, and Long-Term Care Facilities in ASHP Practice Surveys (Recommendation): Lourdes Cuellar (TX)**

That ASHP include small, specialty, critical care, and long-term care facilities in all practice surveys so pharmacy directors in these facilities have the same access to practice benchmarks that community and academic hospitals have.

ASHP includes all types of hospitals (small, critical access, LTAC, specialty) in its surveys, with the exception of the ASHP National Survey (which includes just medical/surgical hospitals and children's hospitals). The National Survey sampling is very specific, dating back many years, partly so that results can be compared from one year to another and to be sure that there is a big enough "n" to allow statistical comparison. For virtually all our other practice surveys, ASHP includes all types of hospitals, but typically don't report results by hospital type because there isn't a big enough sample to do so in a valid way.

**Manufacturer Labeling of Medication Waste Stream (Recommendation): Paul Driver (ID), Erin Fox (UT)**

That ASHP advocate that manufacturers be required to identify required DEQ waste disposal in the product labeling.

The Council on Public Policy discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report.

**Risk Assessment of Health Information Technology (Recommendation): Elizabeth Wade (NH)**

That ASHP provide guidance on the specifics of conducting a post-marketing or retrospective assessment of health information technology (HIT); further, that ASHP advocate that vendors be encouraged to make ongoing enhancements to HIT based on safety feedback from hospitals and health systems.

This recommendation was shared with the ASHP Staff Policy Team as ASHP prepared for the 2014 Council Week. The topic was not added to any council agendas, as ASHP has policies on the risk assessment of HIT and recommends that hospital and health systems perform the appropriate analyses. The development of the tools and methods for completing these assessments has been included as an agenda item for the Section of Pharmacy Informatics and Technology based on this recommendation.

#### **Medical Marijuana (Recommendation): Steve Gray (CA)**

That ASHP develop policy on the use of medical marijuana in health systems.

The Council on Public Policy discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report. Given ongoing state legislation regarding medical as well as recreational marijuana use, the topic is likely to be discussed again at future council meetings.

#### **Role of Simulation in Medication Safety in Pharmacy Training (Recommendation): Dan Degnan (IN), John Hertig (IN), Amy Hyduk (IN), Noelle Chapman (SICP)**

That ASHP develop policy on the use of simulation in pharmacy curricula and continuing education for pharmacists training in medication safety.

The Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report.

#### **Consideration of Indianapolis as a Summer Meetings Site (Recommendation): Dan Degnan (IN), John Hertig (IN), Amy Hyduk (IN)**

That ASHP consider Indianapolis, Indiana as a future site for the ASHP Summer Meetings.

ASHP understands the importance of rotating the host city of our various meetings, conferences, and specialty courses each year. ASHP will explore the potential viability of this venue for one of our meetings. Several criteria are considered in selecting a location and ASHP must keep the following in mind along with other intangibles, such as geography, ease of access for travel, venue – meeting space and hotel access, availability of preferred dates, price, previous experience/evaluation data, and potential for weather impacting success of meeting.

#### **Experiential Experiences (Recommendation): Dale English (OH), Megan Swarthout (MD)**

That ASHP work with ACPE, academic institutions (colleges of pharmacy), and other key stakeholders to require a portion of experiential education hours to be gained outside traditional work schedules (e.g., typical dayshift hours, Monday–Friday, 8 am – 5 pm) to create a more realistic expectation for the employment environment upon licensure as pharmacists.

The Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report.

#### **Preventing Opioid Overdose Through Education and Naloxone Distribution (Recommendation): Roger Woolf (WA), William Jessee (WA), Kathryn Renouard-Brown (WA), Steve Riddle (WA), and Jeffrey Rochon (WA)**

That ASHP support the development and implementation of regulations that permit pharmacists and first responders to furnish opioid reversal agents to prevent opioid-related deaths related to overdose.

The Council on Therapeutics reviewed this recommendation at its September meeting and developed a policy recommendation.

#### **Pharmacist Magnet Program (Recommendation): Darryl Schiller (NJ)**

That ASHP create something similar to the Nursing Magnet Recognition Program to recognize health care organizations for quality patient care, pharmacy excellence, and innovations in professional pharmacy practice.

The suggestion of developing this type of program has come up in the past, and the Council on Pharmacy Practice discussed the possibility of creating such a program for pharmacy in 2004 and then again in 2007. The Council did not recommend developing a parallel program, but rather considering whether excellence in

the medication-use process might be recognized. The language from their minutes follows:

*The Council reviewed the minutes of the 2004 Council's discussion of this subject. Magnet status was not favored by that Council for pharmacy departments as opposed to the entire hospital or health system. Hospital and health-system pharmacy has worked hard to pursue quality through an interdisciplinary approach rather than by singling itself out to be honored for quality. Although there was not complete agreement about the merits of a recognition process, it was the consensus of this year's Council that it would be worthwhile to further investigate the merits, disadvantages, and feasibility of a recognition program for medication use in hospitals and health systems. Some Council members noted that such recognition might help to advance practice. Benefits might accrue in the form of positive internal and external public relations and possibly increased administrative support for pharmacy departments. Some members cited a lack of evidence that such recognition would improve quality of care and noted the difficulty of establishing equitable criteria, given the variation among hospitals and health systems. Some believed that recognition of good medication use already exists via accrediting bodies. Some questioned whether recognizing top performers is a better investment than using the equivalent resources and effort to improve low-performing practices.*

ASHP is exploring approaches and programs consistent with the recommendation from the Council. Such a program would recognize advances in practice, and more specifically, would recognize excellence in medication-use systems, using established best practices and demonstrating a high level of safety and overall quality.

#### **Standardization of Doses and Dosage Formulations (Recommendation): Steve Riddle (WA), Kevin Marvin (VT), Julie Zaucha (OH), Tadd Hellwig (SD), Brenda Denson (AL)**

That ASHP explore the creation of policy dealing with the standardization of dosing and the need for standardized dosage formulations for medications.

The Council on Pharmacy Practice discussed the topic at its September meeting and proposed a policy recommendation. The policy recommendation and a summary of the discussion are contained in the Council's Board Report.

#### **RDC and Affiliate Support (Recommendation): Casey White (TN)**

That ASHP perform periodic review of state affiliate financial support structure to maintain and foster active participation from state affiliates.

This specific recommendation and other delegate-related issues and policies were discussed at the 2014 Commission on Affiliate Relations meeting (see also response to the recommendation below). The discussion was based on data from a survey of affiliates, their policies and procedures, and an analysis of ASHP policies with regard to selection, reimbursement policies and communications with delegates. Commission members were asked to interpret the survey data and make recommendations for maintaining and fostering active participation from state affiliates. The Commission noted several new and revised ASHP programs that support state affiliates, including:

1. Development of new models for affiliate membership promotion by ASHP and affiliates, including a reciprocal membership pilot with six state affiliates, which will run from October 2014 through September 2015. Additionally, an annual joint recruitment letter from the ASHP President and the respective state affiliate president is sent out each January.
2. Increased utilization of Webinar technology to deliver leadership and association management programs to affiliate leaders.
3. Expanded participation of affiliate leaders in training and development meetings, such as the State Affiliate Presidential Officer Retreats, Midyear Clinical and Summer Meeting Affiliate Leader Conferences and other state affiliate events.
4. Increased affiliate involvement in advocacy and professional practice priorities; Providing education and

guidance to states in efforts to promote state legislation on provider status. Actively participating with almost all states on compounding legislation and regulation.

5. Assistance with identifying association management services for six ASHP state affiliates in the last year.

6. Expanded participation in the state affiliate benchmarking survey so that states may assess their performance on an annual basis.

7. Development and implementation of two new revenue-sharing programs for ASHP and affiliates focusing on the technician eLearning portal and ASHP's eBooks.

ASHP will continue (including this year) to review the financial support structure for affiliates. The lifeblood of the entire policy process, including RDCs and the House, rests with our members and affiliates.

Therefore, it is vital that ASHP ensure that the processes we use are maximizing member participation and satisfaction.

#### **ASHP Registration Payment for State Delegates (Recommendation): Vaiyapuri Subramaniam (DC)**

That ASHP pay the full registration for all state delegates at the ASHP Summer Meetings in lieu of paying the \$300 per delegate who attend the Regional Delegate Conferences.

The Commission on Affiliate Relations reviewed ASHP support of affiliates for House of Delegates (HOD) activities at its September meeting. HOD activities include delegate elections, Regional Delegate Conferences (RDC), and the ASHP HOD meeting. The Commission discussed financial support of these activities and programmatic support from ASHP (e.g., suggested policies, surveys, etc.). Commission members did not generally recommend changing the current mechanism for delegate reimbursement to attend an RDC. The advantage to keeping the reimbursement tied to RDC attendance provides incentive for delegates to attend the RDC. Commission members believed that RDCs are valuable in that they provide a forum for delegates to learn about the policies coming to the HOD and for networking and discussion purposes. It was also recommended that ASHP maintain the in-person nature of this meeting. Commission members felt that holding a "virtual" RDC would not provide as much value to ASHP or to the delegates, but that "virtual" meetings could be used as an addition to the face-to-face meetings. However, given that delegates are likely to spend more time in this role with the advent of year-round formalized activities and the rising cost of travel, the Commission suggested that ASHP evaluate increasing the delegate stipend in some form. The Commission made several recommendations for ASHP and affiliates to consider with respect to improving the HOD process. Among them was a suggestion that ASHP continue collecting and sharing various reimbursement policies and communications plans used by affiliates to share them with all state organizations. ASHP made the latest round of this information available in April.

#### **Addition to Rationale of ASHP Policy on Integration of Pharmacy Services in Multifacility Health Systems (Recommendation): Kristy Butler (OR), Kris Marcus (OR), and Michelle Murray (OR)**

That ASHP add a reference to the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive to the rationale of ASHP policy position 1417, Integration of Pharmacy Services in Multifacility Health Systems.

ASHP plans to add this reference to the rationale. Note that the statement has been revised and is an item of business before the House.

#### **Publication of Health-System Pharmacy Benchmarking Data (Recommendation): Elizabeth Shlom (NY)**

That ASHP conduct an annual survey of pharmacy department staffing and workload and publish the results in AJHP.

ASHP publishes pharmacy staffing data in the ASHP National Survey report each year (FTE by bed size and FTE per 100 occupied beds), but only periodically publishes dosing data (doses admin per 100 occupied beds, per patient day or in total), the last being in 2010. ASHP took this recommendation into consideration when it developed the 2015 survey. ASHP avoids referring to the staffing data as a benchmark, since that would imply that it is an industry standard. In reality it is just mean data, but ASHP realizes that it is often

used as a point of comparison.

ASHP wrestles with what data to survey and include in the report. Advice on what types of data would be useful would be of great value to ASHP as that which develops the survey instrument. ASHP wants to make as much useful information available as possible, but also know that data that is difficult to obtain, is inconsistently defined, or is inaccurate, simply won't be reported or won't be useful. In addition to the dosing and staffing information, ASHP collected data on pharmacy consults and interventions for many years but found that the standard deviation was so great and the range of numbers so broad that the data were not meaningful and under-represented what pharmacists were really doing.

ASHP is also exploring what ASHP can offer in benchmarking and productivity reporting, beyond the ASHP National Survey information, but focusing less on doses dispensed and more on medication outcomes.

#### **Removal of Allergenic Excipients (Recommendation): Emily Dyer (VA) and Lisa Deal (VA)**

That ASHP advocate manufacturers remove unnecessary, potentially allergenic excipients (e.g., red dye, yellow dye, gluten) from all medications.

The Council on Pharmacy Practice discussed the topic at its September meeting and proposed a policy recommendation. The policy recommendation and a summary of the discussion are contained in the Council's Board Report.

#### **APPE Rotation Holiday on Residency Match Day (Recommendation): Mark Woods (Past President)**

That ASHP work with colleges of pharmacy and APPE practice sites to cancel rotations on Residency Match Day to reduce student distractions.

This recommendation addresses many good points regarding the student distractions on Residency Match Day. Since there is not currently a master schedule or one body that controls APPE schedules, ASHP will search for mechanisms by which this idea can be pursued. In the fall ASHP raised the topic at the AACP Professional Affairs Committee, where they discussed IPPE and APPE rotations specifically. ASHP will continue to look for other opportunities to bring the suggestion forward to pharmacy schools, including at the Practice Chairs Meeting held at the Midyear each year.

#### **Continuing Education on Ethics (Recommendation): Kathy Donley (OH)**

That ASHP develop programming and enduring educational materials on the subject of ethics to improve members' knowledge base.

ASHP staff will explore ways to re-purpose existing educational materials, such as the Joseph A. Oddis Ethics Colloquium, into enduring products.

#### **Statement on Growth of Restricted Distribution Networks for Prescription Medications (Recommendation): Richard Demers (PA)**

That ASHP develop a statement to minimize the use of restricted distribution networks for new specialty medications.

ASHP councils and task forces have addressed various aspects related to restricted drug distribution systems (RDDS), resulting in a number of policies used to guide ASHP's advocacy, education, and resource development. Due to the continued growth of specialty pharmacy models and the many variations of RDDS, ASHP has been very active in commenting to the FDA on the unintended consequences of RDDS and the growing concerns it has on patients' continuity of care, medication integrity, and undue strain it puts on health systems at transitions of care. ASHP staff and members have served as presenters at two public hearings on this topics held by the FDA.

Additionally, ASHP will continue working with members to develop resources and education on best practices and business models to working with these pharmacy models and/or engage in establishing a specialty pharmacy. Existing resources and ASHP policy include:

- [Specialty Pharmacy Web Resources](#)
- Risk Evaluation and Mitigation Strategies (1002)

- Pharmaceutical Product and Supply Chain Integrity (0907)
- Health-System Use of Medications and Administration Devices Supplied Directly to Patients (0806)
- Importation of Pharmaceuticals (0413)
- Restricted Drug Distribution (0714)

ASHP believes its policy sufficiently addresses the policy aspects of RDDs.

#### **Resource Center for Disease Management Guidelines (Recommendation): Wes Pitts (MS) and Molly Leber (CT)**

That ASHP develop a member resource center for disease management guidelines with push notifications that are customizable to alert members when content is updated.

ASHP staff explored options for developing a member resource center for disease management guidelines, focusing on those with drug therapy. Adding a notification system that would alert members to content updates is also being examined, such as through an RSS feed.

#### **Including Lot Number in Bar Codes of Pharmaceutical Manufacturer Drug Products (Recommendation): Lorraine Lee (CT)**

That ASHP advocate for pharmaceutical manufacturers to include lot number in the bar code of individual products to the unit dose level.

The [ASHP Statement on Bar-Code-Enabled Medication Administration Technology](#) advocates for inclusion of lot number in the bar code of individual products to the unit dose level, and the [FDA plans](#) to roll out that requirement in implementing the DSCSA.

#### **Replacement for ASHP Policy 0914, Education About Patient Safety in Medication-Use Process (Recommendation): Butch Haberber (TX)**

That ASHP develop a new policy to advocate that colleges of pharmacy emphasize instruction on patient safety throughout the medication-use process in didactic and experiential education.

The Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report. The Council noted ASHP's longstanding, extensive commitment to continuing education about patient safety, including conferences devoted entirely to medication safety in conjunction with the ASHP Summer Meetings. The Council believed that a policy was not needed to continue this commitment.

#### **Election Procedure for House of Delegates Chair (Recommendation): Harold Godwin (Past President)**

That ASHP introduce candidates for Chair of the House of Delegates and allow them to present statements at both meetings of the House of Delegates.

This recommendation was shared with the Chair and the ASHP policy development team. ASHP seriously considered the recommendation in planning for the 2015 House of Delegates but concluded that remarks during the second meeting of the House would be redundant with the first meeting as well as the Meet-the-Candidates event and that there not sufficient time in the second meeting for another round of remarks.

#### **Guidance Document on Strategies to Curb Prescription Drug Abuse (Recommendation): Nishaminy Kasbekar (PA)**

That ASHP work with other key stakeholder organizations to develop a consensus guidance document on strategies to curb prescription drug abuse.

This recommendation was discussed by the Council on Pharmacy Practice at its September meeting. A summary of the discussion is contained in the Council's Board Report. The Council proposed a policy recommendation and noted that this will be a prolonged effort that will require ongoing attention.

#### **Education and Training in Medication Safety (Recommendation): Kristy Butler (OR), Kris Marcus (OR), and Michelle Murray (OR)**

That ASHP develop a policy for ongoing CPE on medication safety, similar to ASHP policy 1317, Education and Training in Health Care Informatics Pharmacy.

The Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report. The Council noted ASHP's longstanding, extensive commitment to continuing education about medication-use safety, including conferences devoted entirely to the subject in conjunction with the ASHP Summer Meetings. The Council believed that a policy was not needed to continue this commitment.

**CE Credit for First Meeting of House of Delegates Session (Recommendation): Paul Driver (ID)**

That ASHP explore the possibility of providing CE credit for participation in the first meeting of the House of Delegates.

While ASHP acknowledges that the first HOD session is quite informative, the HOD format does not meet the criteria ACPE has established for continuing pharmacy education (CPE), nor would it be possible to make changes to the ASHP policy development process to make the first session appropriately compliant with ACPE accreditation standards.

**Working Group to Address USP Chapter 800 (Recommendation): Diane Fox (TX), Julie Nelson (TX), Butch Habberger (TX), Jim Wilson (TX)**

That ASHP establish a working group to address issues impacting pharmacy practice when proposed USP Chapter 800 (Hazardous Drugs) is enacted.

ASHP has engaged in an ongoing process of developing and providing comments to USP regarding draft USP Chapter 800. ASHP has established an informal group of ASHP member experts to provide comments and feedback on the current draft version, and they are doing so both verbally and in writing. ASHP is also comparing the content of the chapter to existing related ASHP guidance documents, such as the [ASHP Guidelines on Handling Hazardous Drugs](#). Additionally, ASHP has received a great deal of unsolicited comments that members voicing concern over the current version. ASHP recognizes the importance of getting this chapter right and relies on necessary feedback.

**Risk Assessment of Health Information Technology (Recommendation): Gregory Burger (KS)**

That ASHP encourage colleges of pharmacy to include instruction on quality improvement (QI) tools used in the medication-use process in didactic and experiential education, and to support the development of postgraduate, curriculum-based QI process improvement training programs (CE, webinars, conventions) to foster and increase the number of pharmacists with QI process expertise.

The ASHP [Quality Improvement Web Resource Center](#) provides a variety of tools and resources, including a separate section on education, including CE, webinars, podcasts, and more. In addition, the Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council's Board Report.

**Editorial Change to ASHP Policy 1415, Credentialing, Privileging, and Competency Assessment (Recommendation): Marjorie Shaw Phillips (GA, on behalf of GA, AL, CA, FL, ID, KY, LA, MD, MT, NE, OH, OR, SD, TX, DC, WI, OK, NH, WY, MO, ME, NV, KS, TN, NC, RI, SC, MS, AK, IL)**

That ASHP remove the word "independently" from the third clause of ASHP policy 1415, so that it reads: "To recognize that pharmacists are responsible for maintaining competency to practice in direct patient care."

This change was made.

**Timely Update of Ordering/Prescribing Databases (Recommendation): Kevin Marvin (VT)**

That ASHP advocate for timely updates of ordering and prescribing medication databases within EHR systems throughout the continuum in support of safe and efficient patient care.

This recommendation was added as an agenda item for the Council on Pharmacy Management. ASHP looked at the Interoperability of Patient Care Technologies in 2012 and voted to recommend a policy that encouraged integration, consolidation, and harmonization of medication-related databases used in patient-care technologies. Additionally, it is important to ensure that databases used in patient care reduce the risk that outdated, inaccurate, or conflicting data might be used in the care of patients.

### **Statement on the Criteria for an Intermediate Category of Drug Products (Recommendation): Kevin Marvin (VT)**

That ASHP review and update the ASHP Statement on the Criteria for an Intermediate Category of Drug Products to include the safe operational implementation requirements of such a medication category and to identify pharmacist involvement with this category of medications as pharmacist collaborative medication therapy management supporting optimal patient care.

ASHP had reviewed this statement as recently as 2012 (Council on Therapeutics), and in 2011 the Council on Therapeutics discussed the issue of a “Behind-the-Counter” designation during the discussion on the safety and effectiveness of proposed nonprescription status for oral contraceptives. With the recent activity and changes in state legislation regarding behind-the-counter designation and recommendations made by the Food and Drug Administration the Council on Therapeutics, reviewed the statement at its September meeting and voted to revise the statement. A summary of the discussion is contained in the Council’s Board Report.

### **Revision of ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records (Recommendation): Jill Bates (SCSS), Christopher Betz (SCSS)**

That ASHP revise the Guidelines on Documenting Pharmaceutical Care in Patient Medical Records to strengthen the tone, update the content to support PPMI Recommendations B15 and B6, and promote standardization of documentation practices within the profession to enhance patient care.

This recommendation was referred to the Council on Pharmacy Practice to work in collaboration with the Section on Pharmacy Informatics and Technology on the revision of the guidelines.

### **Women in Pharmacy Leadership (Recommendation): Lourdes Cuellar (TX)**

That ASHP develop educational activities and establish a mentoring program to encourage and support the rapidly evolving role of women in pharmacy leadership in hospitals and health systems.

ASHP hosted a webinar roundtable, [Fostering Women Leaders in a Knowledge Café](#), on March 4, 2015. ASHP will continue to foster discussion of and education regarding leadership role for women in pharmacy.

### **Cultural Competence and Diversity of Workforce (Recommendation): Lourdes Cuellar (TX)**

That ASHP return ASHP policy 1414, Cultural Competency and Cultural Diversity, to the Council on Education and Workforce Development for revision to recognize the important distinctions between cultural competence and an ethnically diverse workforce.

The Council on Education and Workforce Development discussed the topic at its September meeting. A summary of the discussion is contained in the Council’s Board Report.

# Professional Policies Approved by the 2015 ASHP Virtual House of Delegates

Bethesda, MD

November 20, 2015

Am J Health-Syst Pharm. 2016; 73:e1

The new professional policies approved by the ASHP House of Delegates at its inaugural virtual session are listed below. Policies proposed by councils or other ASHP bodies are first considered by the Board of Directors and then acted on by the House of Delegates, which is the ultimate authority for ASHP positions on professional issues. The background information on these policies appears on the ASHP Web site ([www.ashp.org](http://www.ashp.org)); click on “Practice and Policy” then on “House of Delegates,” and then on “Policies Approved by the Nov. 2015 Virtual House.”

## 1535

### Nonproprietary Naming of Biological Products

Source: Council on Public Policy

To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further,

To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.

## 1536

### Appropriate Use of Testosterone

Source: Council on Therapeutics

To educate pharmacists, patients, and the public about the risks and benefits of testosterone use and about best practices for safe handling of testosterone, specifically regarding harmful effects of contact with another person; further,

To educate healthcare providers about the importance of including accurate testosterone levels and confirmed evidence of clinical symptoms in the evaluation of candidates for testosterone therapy; further,

To encourage additional research on the long-term effects of testosterone therapy.

## 1537

### ASHP Statement on the Roles of Pharmacy Technicians\*

To approve the ASHP Statement on the Roles of Pharmacy Technicians.

\*The ASHP statement approved by the virtual House of Delegates is available on the ASHP Web site ([www.ashp.org](http://www.ashp.org)). Under “Practice and Policy,” click on “Policy Positions & Guidelines” and then on “New Guidance Documents.”

**HOUSE OF DELEGATES**  
**Amber Lucas, Chair**  
**November 13-20, 2015**  
**FINAL ROSTER**

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Lisa Gersema, President-Elect			
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Donald Letendre, Board Liaison, Council on Education and Workforce Development			
Kelly Smith, Board Liaison, Council on Public Policy			
Kathy Pawlicki, Board Liaison, Commission on Affiliate Relations			
Tim Brown, Board Liaison, Council on Therapeutics			
Jennifer Schultz			
Todd Karpinski			
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Fred Eckel	R. Paul Baumgartner	Bruce Canaday	David Zilz
Harold Godwin	Philip J. Schneider	Gerald Meyer	
<b>STATE</b>	<b>DELEGATES</b>		
<b>Alabama (3)</b>	Kimberley Benner Pamela Stamm Whitney White		
<b>Alaska (2)</b>	Sara Doran-Atchison Ashley Schaber		
<b>Arizona (3)</b>	Melinda Throm Burnworth Christi Jen Carol Rollins		
<b>Arkansas (2)</b>	Zhiva Brown Rayanne Story		
<b>California (8)</b>	Christine Antczak Annet Arakelian Victoria Ferraresi Brian Kawahara Elaine Law Julie Lenhart Stacey Raff Kethen So		

<b>STATE</b>	<b>DELEGATES</b>
<b>Colorado (3)</b>	Patricia Killingsworth Ashley Mains Espinosa Joel Marrs
<b>Connecticut (3)</b>	Molly Leber Lorraine Lee Michelle Then
<b>Delaware (2)</b>	Francine Farnsworth Lisa Deal
<b>Florida (5)</b>	Deborah Brown Jennifer Burnette Christine Gegeckas Suzanne Turner Antonia Zapantis
<b>Georgia (3)</b>	Michael Melroy Christy Norman Rondell Jagers
<b>Hawaii (2)</b>	
<b>Idaho (2)</b>	Michael Dickens Elizabeth Thompson
<b>Illinois (5)</b>	Travis Hunerdosse Ann Jankiewicz Jennifer Phillips Carrie Sincak
<b>Indiana (3)</b>	Denise Fields John Hertig Amy Hyduk
<b>Iowa (3)</b>	John Hamiel Lisa Mascardo David Weetman
<b>Kansas (3)</b>	Christopher Bell Gregory Burger Joan Kramer
<b>Kentucky (3)</b>	Margo Ashby Megan Brafford
<b>Louisiana (3)</b>	Michael Cockerham Jennifer Smith
<b>Maine (2)</b>	Paul Barrett Tyson Thornton
<b>Maryland (4)</b>	Patricia Grunwald Asha Tata Kristine Parbuoni
<b>Massachusetts (4)</b>	Nicole Clark Margarita DiVall Ross Thompson Snehal Bhatt

<b>STATE</b>	<b>DELEGATES</b>
<b>Michigan (4)</b>	Ryan Bickel Gary Blake Peggy Malovrh Michael Ruffing
<b>Minnesota (3)</b>	Kristi Gullickson Paul Krogh John Pastor
<b>Mississippi (2)</b>	Wesley Pitts
<b>Missouri (3)</b>	Nicole Allcock Joel Hennenfent Amy Sipe
<b>Montana (2)</b>	Lonnye Finneman Amanda Patel
<b>Nebraska (3)</b>	Michele Poepping-Faulkner Donna Soflin Jerome Wohleb
<b>Nevada (2)</b>	Adam Porath
<b>New Hampshire (2)</b>	Elizabeth Wade
<b>New Jersey (4)</b>	Robert Adamson Luigi Brunetti Timothy Reilly Paul Goebell, III
<b>New Mexico (2)</b>	Juliann Horne
<b>New York (5)</b>	Leigh Briscoe-Dwyer Joe Pinto Stephanie Seyes Elizabeth Shlom Mark Sinnett
<b>North Carolina (4)</b>	Stephen Eckel Mary Parker Dennis Williams
<b>North Dakota (2)</b>	Nicholas Helbling Maari Loy
<b>Ohio (5)</b>	Kathleen Donley Margaret Huwer Karen Kier Scott Knoer Julie Zaucha
<b>Oklahoma (3)</b>	Ann Lloyd Edna Patatanian Darin Smith
<b>Oregon (3)</b>	Majid Tanis Deanna Moretz Michelle Murray

<b>STATE</b>	<b>DELEGATES</b>
<b>Pennsylvania (5)</b>	Nishaminy Kasbekar Patricia Kienle Richard Pacitti Jean Scholtz Matthew Scola
<b>Puerto Rico (2)</b>	Meredith Velez Mercado
<b>Rhode Island (2)</b>	Ena Dwierzynski Linda Nelson
<b>South Carolina (3)</b>	Heather Easterling Joel Murphy Robert Spires
<b>South Dakota (2)</b>	Katie Hayes Tadd Hellwig
<b>Tennessee (3)</b>	Brandon Edgeron Jeanne Ezell Micah Cost
<b>Texas (6)</b>	Lourdes Cuellar Tricia Meyer Julie Nelson Lance Ray James Wilson
<b>Utah (3)</b>	Elyse MacDonald Leigh Fritz Krystal Moorman
<b>Vermont (2)</b>	Kevin Marvin Jeffrey Schnoor
<b>Virginia (4)</b>	Emily Dyer Rodney Stiltner Eric Maroyka Steven LaHaye
<b>Washington, D.C. (2)</b>	Monique Bonhomme John Quinn
<b>Washington State (4)</b>	Steven Riddle Roger Woolf
<b>West Virginia (2)</b>	Justin Hare Carol Woodward
<b>Wisconsin (4)</b>	Terry Audley Arlene Iglar Ryan Miller Michelle Thoma
<b>Wyoming (2)</b>	Linda Gore-Martin Kirsi Ludwig
<b>SECTIONS AND FORUMS</b>	<b>DELEGATES</b>
<b>Ambulatory Care Practitioners</b>	Kelly Epplen

<b>STATE</b>	<b>DELEGATES</b>
<b>Clinical Specialists and Scientists</b>	Curtis Collins
<b>Inpatient Care Practitioners</b>	Emily Alexander
<b>Pharmacy Informatics and Technology</b>	Brandon Ordway
<b>Pharmacy Practice Managers</b>	James Hoffman
<b>New Practitioners Forum</b>	Joshua Fleming
<b>Pharmacy Student Forum</b>	Kristina Lantis
<b>FRATERNAL</b>	<b>DELEGATES</b>
<b>U.S. Air Force</b>	Winnie Lok-Park
<b>U.S. Army</b>	Stacey Causey
<b>U.S. Public Health Service</b>	Randy Seys
<b>Veterans Affairs</b>	Julie Groppi

(**Note:** The number next to the state listing denotes the number of delegates allotted to that state, which may vary from the actual number of delegates voting in the November virtual House.)