Proceedings of the 60th annual session of the ASHP House of Delegates
June 8 and 10, 2008
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HENRI R. MANASSE, JR., SECRETARY

The 60th annual session of the ASHP House of Delegates was held at the Washington State Convention and Trade Center, in Seattle, WA, in conjunction with the 2008 Summer Meeting.

First meeting

The first meeting was convened at 2:00 p.m. Sunday, June 8, by Chair of the House of Delegates Teresa J. Hudson. Kevin J. Coigan, Vice Chair of the Board of Directors, gave the invocation.

Chair Hudson introduced the persons seated at the head table: Cynthia Brennan, Immediate Past President of ASHP and Vice Chair of the House of Delegates; Janet A. Silvester, President of ASHP and Chair of the Board of Directors; Henri R. Manasse, Jr., Executive Vice President and Chief Executive Officer of ASHP and Secretary of the House of Delegates; and Joy Myers, Parliamentarian.

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

The roll of official delegates was called. A quorum was present, including 195 delegates representing 49 states, the District of Columbia and Puerto Rico, delegates from the federal services, chairs of the sections and forums, ASHP officers, members of the Board of Directors, and ASHP past presidents.

Chair Hudson reminded delegates that the report of the 59th 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 59th House of Delegates session were received without objection.

Chair Hudson called on Dan D. Degnan for the report of the Committee on Nominations. Nominees were presented as follows:

President-elect

Diane B. Ginsburg, M.S., FASHP, Clinical Professor, Division of Pharmacy Practice, Assistant Dean for Student Affairs, University of Texas at Austin, College of Pharmacy

Lynnae M. Mahaney, M.B.A., FASHP, Chief, Pharmacy Service, Wm. S. Middleton Memorial VA Hospital, Madison, WI

Board of Directors (2009–2012)

David D. Allen, Ph.D., FASHP, Dean of Pharmacy and Professor of Pharmaceutical Sciences, Northeastern Ohio Universities College of Pharmacy, Rootstown, OH

Wayne S. Boheneck, Pharm.D., M.S., FASHP, Vice President, Patient Safety and Clinical Transformation, Catholic Healthcare Partners, Cincinnati, OH

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

Rita K. Jew, Pharm.D., FASHP, Executive Director, Department of Pharmacy Services, Children’s Hospital of Orange County, Orange, CA

Chair, House of Delegates

Teresa J. Hudson, Pharm.D., BCPP, FASHP, Center Co-Principal Investigator and Research Health Scientist, VA Center for Mental Healthcare & Outcomes Research, North Little Rock, AR

Gerald E. Meyer, B.S., M.B.A., Pharm.D., FASHP, Director of Experiential Education, Thomas Jefferson University, Jefferson School of Pharmacy, Philadelphia, PA

A “Meet the Candidates” session to be held on Monday, June 9, was announced.

Chair Hudson announced the candidates for the executive committees of the five sections of ASHP.
Report of President and Chair of the Board. President Silvester referred to the 2007 ASHP Annual Report, "Full Steam Ahead," which had been distributed to delegates along with summaries of actions taken by the Board of Directors over the past year. She 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.

President Silvester, on behalf of the Board of Directors, then moved adoption of the proposed ASHP Statement on Bar-Code-Enabled Point-of-Care Technology, which was developed by the Executive Committee of the Section of Pharmacy Informatics and Technology. Delegates voted to change the term "Bar-Code-Enabled Point-of-Care (BPOC)" to "Bar-Code-Enabled Medication Administration (BCMA)" throughout the document, and the amended policy statement was adopted. (Note: This statement supersedes ASHP policy 0308.)

Report of Treasurer. Paul W. Abramowitz presented the report of the Treasurer. There was no discussion, and the delegates voted to accept the Treasurer’s report.

Report of Executive Vice President. Henri R. Manasse, Jr., presented the report of the Executive Vice President.

Recommendations. Chair Hudson called on members of the House of Delegates for Recommendations. See the Appendix for a complete listing of all Recommendations.

Policy committee reports. Chair Hudson outlined the process used to generate policy committee reports. She announced that the recommended policies from each council would be introduced as a block. She further advised the House that any delegate could raise questions and discussion without having to “divide the question” and that a motion to divide the question is necessary only when a delegate desires to amend a specific proposal or to take an action on one proposal separate from the rest of the report; requests to divide the question are granted automatically unless another delegate objects.

Chair Hudson also announced that she would experiment with a new procedure under which 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.)

Stanley S. Kent, Board Liaison to the Council on Pharmacy Management, presented the Council’s Policy Recommendations A through D.

A. 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.

*B. ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems

To approve the ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems, with the deletion of lines 69-71: ASHP best practices have been used as guidance by regulatory and accrediting bodies such as CMS, state boards of pharmacy, and the Joint Commission, as well as by courts of law.

*C. Health-System Use of Medications and Administration Devices Supplied Directly to Patients

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

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

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

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

(Note: This policy supersedes ASHP policy 0706.)
D. Human Immunodeficiency Virus (HIV) Positive Employees

To discontinue policy 9201, Human Immunodeficiency Virus (HIV) Positive Employees, which reads:

To adopt the position that mandatory routine testing of health care workers for infection with the human immunodeficiency virus is unnecessary; further,

To support the use of universal precautions for infection control.

James G. Stevenson, Board Liaison to the Council on Pharmacy Practice, presented the Council's Policy Recommendations A through E.

A. ASHP Statement on Pharmacy Services to the Emergency Department

To approve the ASHP Statement on Pharmacy Services to the Emergency Department.

B. ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System

To approve the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System.

(Note: This statement supersedes the ASHP Statement on the Pharmacy and Therapeutics Committee dated November 20, 1991, and the ASHP Statement on the Formulary System dated November 18, 1982.)

*C. Standardization of Intravenous Drug Concentrations

To develop nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given as continuous infusions; further,

To encourage all hospitals and health systems to use infusion devices that interface with hospital their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities.

*D. Disclosure of Excipients in Drug Products

To advocate that manufacturers declare and codify the name and derivative source of all excipients in drug products on the official label and in the Structured Product Labeling.

(Note: “Derivative source” means the botanical, animal, or other source from which the excipient is originally derived.)

*E. Biological Drugs

To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of medications derived from biologic sources therapies, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

To facilitate education of pharmacists about the proper use of medications derived from biologic sources therapies.

(Note: Section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] defines biological product as follows: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine [or any other trivalent organic arsenic compound], applicable to the prevention, treatment, or cure of a disease or condition of human beings.)

Sheila L. Mitchell, Board Liaison to the Council on Public Policy, presented the Council's Policy Recommendations A through G.

A. Education, Prevention, and Enforcement Concerning Workplace Violence

To advocate that federal, state, and local governments recognize the risks and consequences of workplace violence in the pharmacy community and enact appropriate criminal penalties; further,

To collaborate with federal, state, and local law enforcement and other government authorities on methods for early detection and prevention of workplace violence; further,

To encourage all workplace environments to develop and implement a policy for pharmacy personnel that (1) educates about prevention and deterrence of workplace violence, (2) identifies escalating situations that can lead to violence and instructs employees on protection and self-defense, (3) provides continued support and care to heal personnel who were directly or indirectly involved in a incident of workplace violence; further,

To encourage the health care community to develop and maintain a communication network to share information about incidents of potential and real workplace violence.
**B. Regulation of Dietary Supplements**

To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling and including disclosure of excipients; (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and (4) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met: (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective; (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer; (3) the advertising includes a recommendation to consult with a health care professional before initiating use; (4) any known warnings or precautions regarding dietary supplement—medication interactions or dietary supplement—disease interactions are provided as part of the advertising; and (5) the advertising is educational in nature and includes pharmacists as a source of information.

(Note: "Dietary supplement" as used in this policy is defined by the Dietary Supplement Health and Education Act of 1994, as amended; 21 U.S.C. 321.)

(Note: This policy supersedes ASHP policy 0718.)

**C. Appropriate Staffing Levels**

To advocate that pharmacists pharmacy leadership at each practice site establish the site’s pharmacist and technician staffing levels on the basis of patient safety considerations, taking into account factors such as (1) acuity of care, (2) breadth of services, (3) historical safety data, and (4) results of research on the relationship between staffing patterns and patient safety; further,

To advocate that regulatory bodies not mandate specific, uniform pharmacy personnel ratios but rather ensure that site-specific staffing levels optimize patient safety; further,

To encourage additional research on the relationship between pharmacy staffing patterns and patient safety.

(Note: This policy supersedes ASHP policy 0717.)

**D. Medicare Prescription Drug Benefit**

To strongly advocate a fully funded prescription drug program for eligible Medicare beneficiaries that maintains continuity of care and ensures the best use of medications; further,

To advocate that essential requirements in the program include (1) appropriate product reimbursement; (2) affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services, based on a study of those costs; (4) appropriate coverage and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient’s choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

(Note: "Fully funded" means the federal government will make adequate funds available to fully cover the Medicare program’s share of prescription drug program costs; “eligible” means the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.)

(Note: This policy supersedes ASHP policy 0721.)

**E. Federal Review of Anticompetitive Practices by Drug Product Manufacturers**

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

To encourage appropriate federal review of these practices.

(Note: This policy supersedes ASHP policy 0520.)

**F. Confidentiality of Patient Health Care Information**

To approve the ASHP Statement on Confidentiality of Patient Health Care Information.

(Note: This statement supersedes the 1999 version of the document.)

**G. Uniform State Laws Regarding Pharmacy Technicians**

To advocate that pharmacy move toward the following model with respect to technicians as the optimal approach to protecting public health and safety: (1) development and adoption of uniform state laws and regulations regarding pharmacy technicians; (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy
technician certification, and (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to the state board of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

To advocate registration of pharmacy technicians by state boards of pharmacy; further,

To advocate, with respect to certification, as an interim measure until the optimal model is fully implemented, that individuals be required either (1) to have completed an ASHP-accredited program of education and training or (2) to have at least one year of full-time equivalent experience as pharmacy technicians before they are eligible to become certified; further,

To advocate that licensed pharmacists be held accountable for the quality of pharmacy services provided and the actions of pharmacy technicians under their charge.

(Note: Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Registration is the process of making a list or being enrolled in an existing list; registration should be used to help safeguard the public through interstate and intrastate tracking of the technician work force and preventing individuals with documented problems from serving as pharmacy technicians.)

(Note: This policy supersedes ASHP policy 0412.)

Lynnae M. Mahaney, Board Liaison to the Council on Therapeutics, presented the Council’s Policy Recommendations A through D.

*A. ASHP Statement on Criteria for an Intermediate Category of Drug Products

To approve the ASHP Statement on Criteria for an Intermediate Category of Drug Products, with the deletion of the following phrase in lines 60-61: a six-year doctor of pharmacy degree.

B. Pharmacist’s Leadership Role in Anticoagulation Therapy Management

To advocate that pharmacists provide leadership in the interdisciplinary development, implementation, maintenance, effectiveness monitoring, and assurance of continuity of care of anticoagulation management programs; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients within anticoagulation management programs; further,

To encourage pharmacists who participate in anticoagulation programs to educate patients, caregivers, prescribers, and staff about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, and recommended laboratory testing and other monitoring.

*C. Generic Substitution of Narrow Therapeutic Index Drugs

To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

To oppose a blanket restriction on generic substitution for any medication or medication class without evidence from in the absence of well-designed, independent studies that demonstrate provide evidence of inferior efficacy or safety of the generic drug product compared with the innovator.

D. Dietary Supplements Containing Ephedrine Alkaloids

To discontinue ASHP policy 0302, which reads:

To support a ban on the manufacture and sale of dietary supplements containing ephedrine alkaloids because (1) ephedrine alkaloids pose a significant risk of illness and injury, (2) changes in product labeling are not adequate to protect the public from these dangers, (3) the use of these products represents significant expenditures for a health-related remedy of unsubstantiated value, and (4) other safe and effective interventions are available for all common uses of these products.

Diane B. Ginsburg, Board Liaison to the Council on Education and Workforce Development, presented the Council’s Policy Recommendations A through D.

*A. Role of Pharmacy Interns

To foster advocate for changes in state practice acts and regulations that would define a scope of practice for pharmacy interns that is distinct from that of not limited to that of a pharmacy technician; further,

To explore and promote new staffing models that foster expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.
B. Standardized Pharmacy Technician Training as a Prerequisite for Certification

To advocate that completion of an ASHP-accredited pharmacy technician training program be a prerequisite for the Pharmacy Technician Certification Examination.

C. Collaboration Regarding Experiential Education

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

D. Entry-Level Doctor of Pharmacy Degree

To be an active participant in the Accreditation Council for Pharmacy Education (ACPE) process for the revision of accreditation standards for entry-level education in pharmacy; further,

To actively monitor the long-range impact that the single entry-level degree will have on residency education, availability of experiential training sites, graduate education, and continuing education programs, and the resulting health-system pharmacist applicant pool.

(Note: This policy supersedes ASHP policy 9809.)

Candidates for the position of Chair of the House of Delegates made brief statements to the House of Delegates. The meeting adjourned at 5:30 p.m.

Second meeting

The second and final meeting of the House of Delegates session convened on Tuesday, June 10, at 4:30 p.m. A quorum was present.

Election of House Chair

Chair Hudson announced the appointment of alternate delegates as tellers to canvas the ballots for the election of Chair of the House of Delegates. Those appointed were Diane Lynn Fox (TX), Robert Parsons (OH), and Patricia Mattingly Wegner (IL).

Chair Hudson instructed tellers on the distribution and collection of ballots to registered delegates. After the balloting process, tellers left the assembly to count the ballots while the business of the House proceeded.

Board of Directors duly considered matters. The Board reported on 11 professional policies that were amended at the first House meeting. Pursuant to Bylaws section 7.3.1.1, the Board met on the morning of June 10, 2008, to "duly consider" the amended policies. The Board presented its recommendations as follows:

1. ASHP Statement on Bar-Code-Enabled Medication Administration Technology: The Board agreed that the amended language was acceptable.

2. Council on Pharmacy Management, Policy B, "ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems": The Board agreed that the amended language was acceptable.

3. Council on Pharmacy Management, Policy C, "Health-System Use of Medications and Administration Devices Supplied Directly to Patients": The Board agreed that the amended language was acceptable with editorial changes. As edited, the policy reads as follows:

C. Health-System Use of Medications and Administration Devices Supplied Directly to Patients

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

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

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

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

(Note: This policy supersedes ASHP policy 0706.)

4. Council on Pharmacy Practice, Policy C, "Standardization of Intravenous Drug Concentrations": The Board agreed that the amended language was acceptable with editorial changes. As edited, the policy reads as follows:

C. Standardization of Intravenous Drug Concentrations

To develop nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given as continuous infusions; further,
To encourage all hospitals and health systems to use infusion devices that interface with their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities.

5. Council on Pharmacy Practice, Policy D, “Disclosure of Excipients in Drug Products”: The Board encouraged delegates to reconsider the original policy proposal. Following a motion to reconsider the original language the policy was adopted as originally presented. The policy reads as follows:

   D. Disclosure of Excipients in Drug Products

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

   (Note: “Derivative source” means the botanical, animal, or other source from which the excipient is originally derived.)

   6. Council on Pharmacy Practice, Policy E, “Biological Drugs”: The Board agreed that the amended language was acceptable. The title of the policy has been changed to “Medications Derived from Biologic Sources.”

   7. Council on Public Policy, Policy B, “Regulation of Dietary Supplements”: The Board agreed that the amended language was acceptable with editorial changes. As edited, the policy reads as follows:

   B. Regulation of Dietary Supplements

   To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling that includes disclosure of excipients; (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and (4) establish and maintain an adverse event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

   To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met: (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective; (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer; (3) the advertising includes a recommendation to consult with a health care professional before initiating use; (4) any known warnings or precautions regarding dietary supplement—medication interactions or dietary supplement—disease interactions are provided as part of the advertising; and (5) the advertising is educational in nature and includes pharmacists as a source of information.

   (Note: Dietary supplement as used in this policy is defined by the Dietary Supplement Health and Education Act of 1994, as amended; 21 U.S.C. 321.)

   8. Council on Public Policy, Policy C, “Appropriate Staffing Levels”: The Board encouraged delegates to reconsider the policy and adopt revised language. A motion was made to reconsider and the revised policy proposed by the Board was adopted. The policy reads as follows:

   C. Appropriate Staffing Levels

   To advocate that pharmacists at each practice site base the site’s pharmacist and technician staffing levels on patient safety considerations, taking into account factors such as (1) acuity of care, (2) breadth of services, (3) historical safety data, and (4) results of research on the relationship between staffing patterns and patient safety; further,

   To advocate that regulatory bodies not mandate specific, uniform pharmacy personnel ratios but rather ensure that site-specific staffing levels optimize patient safety; further,

   To encourage additional research on the relationship between pharmacy staffing patterns and patient safety.

   (Note: This policy supersedes ASHP policy 0717.)


   10. Council on Therapeutics, Policy C, “Generic Substitution of Narrow Therapeutic Index Drugs”: The Board agreed that the amended language was acceptable with editorial changes. As edited, the policy reads as follows:

   C. Generic Substitution of Narrow Therapeutic Index Drugs

   To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

   To oppose a blanket restriction on generic substitution for any medication or medication class without evidence from
well-designed, independent studies that demonstrate inferior efficacy or safety of the generic drug product.

11. Council on Education and Workforce Development, Policy A, “Role of Pharmacy Interns” The Board agreed that the amended language was acceptable with editorial changes. As edited, the policy reads as follows:

A. Role of Pharmacy Interns

To advocate for changes in state practice acts and regulations that would define a scope of practice for pharmacy interns that is not limited to that of a pharmacy technician; further,

To explore and promote new staffing models that foster expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

New Business. Chair Hudson announced that, in accordance with Article 7 of the Bylaws, there were three items of New Business to be considered.

Chair Hudson called on John Poikonen (MA) to introduce the item of New Business, titled “AJHP Green Initiative.” Following discussion, the item was approved for referral. It reads as follows:

AJHP Green Initiative

Motion: Members should be able to opt out of having a hard copy of the American Journal of Health System Pharmacy (AJHP) mailed to them.

Background: Some members utilize the on-line version of AJHP exclusively. Some have not opened the AJHP packaging for years and should have the option to opt out of receiving the biweekly packaging, if on-line access is the preferred method of knowledge acquisition. Advertisers are not getting the value of members throwing away the paper version of AJHP without even opening the package. Many medical journals have moved to an online advertising model to make up any revenue shortfalls, so too should AJHP.

Suggested Outcome: AJHP should allow members the option to opt out of receiving the hard copy of the journal.

Chair Hudson then called on Ernest Dole, Chair, Section of Home, Ambulatory, and Chronic Care Practitioners, to introduce the second item of New Business, titled “Collaborative Drug Therapy Management.” Following discussion, the item was approved for referral. It reads as follows:

Collaborative Drug Therapy Management

Motion: To review ASHP policy 0318 for improved language that will ensure that it is consistent with existing ASHP policies and vision, and to increase flexibility and enhance efforts of ASHP to achieve components of its leadership agenda, including pharmacist provider status by third-party payors such as Centers for Medicare and Medicaid Services (CMS).

Background: ASHP should reconsider policy 0318 due to its inconsistencies with other ASHP policies, ASHP leadership agenda, and ASHP vision. ASHP policy 0318 states the following in the first paragraph:

“To recognize licensure of pharmacists as the only state-imposed legal requirement necessary for pharmacists engaged in providing collaborative drug therapy management services; further,…”

The following policies and ASHP documents are in direct conflict with policy 0318:

1. Policy 0005, Residency training for pharmacists who provide direct patient care
2. Policy 0701, Requirement for residency
3. Policy 0307, Product reimbursement and pharmacist compensation
4. Policy 0006, Pharmacist credentialing
5. Policy 9812, Collaborative drug therapy management
6. 2008 Council on Public Policy report: The report discusses the need to revise 0318
7. 2007–08 ASHP Leadership Agenda: Expand access to the patient care services of hospital and health-system pharmacists
8. 2008–09 ASHP Leadership Agenda: Foster optimal models for the deployment of pharmacy resources in hospital and health systems
9. ASHP Long-range vision for the pharmacy work force in hospitals and health systems (AJHP 2007; 64:1321, 24, 26)

Suggested Outcome: Revise policy 0318 to ensure consistency with other ASHP policies and workforce vision.

Chair Hudson then called on Judy Schneider (MN) to introduce the item of New Business, titled “Term of the Chair of the House of Delegates.” Following discussion, the item was defeated.

Recommendations. Chair Hudson called on members of the House of Delegates for Recommendations. See the Appendix for a complete listing of all Recommendations.

Recognition. Chair Hudson recognized members of the Board who were continuing in office. She also introduced members of the Board who were completing their terms of office.
As a token of appreciation on behalf of the Board of Directors and members of ASHP, Chair Hudson presented Immediate Past President Silvester with an inscribed gavel commemorating her term of office. Dr. Silvester recognized the service of Chair Hudson as Chair of the House of Delegates and a member of the Board of Directors.

Chair Hudson recognized Cynthia Brennan's years of service as a member of the Board, in various presidential capacities, as Chair of the Board, and as Vice Chair of the House of Delegates.

Chair Hudson then installed the chairs of ASHP's sections and forums: Kelly Smith, Chair of the Section of Clinical Specialists and Scientists; Marc Stranz, Chair of the Section of Home, Ambulatory and Chronic Care Practitioners; Randy Kuiper, Chair of the Section of Inpatient Care Practitioners; Dennis Tribble, Chair of the Section of Pharmacy Informatics and Technology; James Rinehart, Chair of the Section of Pharmacy Practice Managers; Elaine Huang, Chair of the Pharmacy Student Forum; and Lindsey Kelley, Chair of the New Practitioners Forum.

Dr. Hudson then recognized the remaining members of the executive committees of sections and forums.

Chair Hudson then called on Vice Chair Brennan to preside over the House for the remainder of the meeting.

Vice Chair Brennan announced that Teresa J. Hudson had been elected as Chair of the House.

Installation. Vice Chair Brennan installed Kevin J. Colgan as President of ASHP, John A. Armitstead and Janet L. Mighty as members of the Board of Directors, and Teresa J. Hudson as Chair of the House of Delegates.

Parliamentarian. Vice Chair Brennan thanked Joy Myers for ten years of service to ASHP as parliamentarian.

Adjournment. The 60th annual session of the House of Delegates adjourned at 5:51 p.m.

"The Committee on Nominations consisted of Dan Degnan (IN), Chair; Cynthia Brennan (WA), Vice Chair; Ernest R. Anderson (MA), Thomas J. Johnson (SD), Risa C. Rahm (TN), Ranee M. Runnebaum (MO), and Therese M. Wavrin (OR)."
2008 House of Delegate Recommendations

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.

Recommendations by Delegates on Sunday, June 8:

1. Caryn Bing (NV): Multi-Site and Geographically Dispersed Pharmacy Residency Programs

Recommendation: The ASHP Board of Directors should 1) request that the ASHP Commission on Credentialing evaluate and develop clear criteria and methods for accreditation of multi-site and geographically dispersed residency programs, and 2) allocate appropriate resources to support effective implementation of pharmacy residency accreditation of programs that may be centrally managed and offered in multiple geographic locations, including residencies offered in alternate sites of practice.

Background: Unlike the ASHP Technician Training Program Accreditation model, ASHP's current residency accreditation system does not facilitate accreditation of single residency programs with geographically dispersed practice site locations and with the management structure typical of large multi-site regional or multi-state organizations. This effectively limits the development and expansion of pharmacy residencies in alternate sites of practice.

2. Michael W. Kelly (IA), Kelly M. Smith (KY), Ted L. Rice (PA), Marie A. Chisholm-Burns (AZ), Erin R. Fox, (UT), and Susan Goodin (NJ): Safe Handling and Preparation of Gene Therapy Agents

Recommendation: ASHP should develop guidelines on the safe handling and preparation of gene therapy agents.

Background: With the increasing use of gene therapy in cancer, Parkinson’s disease, cardiovascular disease, and other chronic conditions, pharmacy standards need to be established for the safe handling and preparation of these therapies. There are European standards and institution-specific policies but no uniform best practices exist in the United States for practitioner guidance.

3. Helen M. Calmes (LA): Black Box Warnings

Recommendation: ASHP should explore how to handle FDA black box warnings and offer guidance to the membership.

Background: The Section of Inpatient Care Practitioners (SICP) Section Advisory Group (SAG) on Medication Safety has discussed FDA black box warnings extensively on its listserv. Numerous questions have emerged about how to manage such warnings. The SICP SAG felt that in keeping with ASHP’s goal of promoting safe medication use, ASHP should help the membership understand what to do in response to such warnings via alerts, actions, guidance documents, and work with regulatory agencies and accrediting bodies (e.g., TJIC, CMS).


Recommendation: ASHP should work to eliminate use of the terms “transcribe” and “transcribing” from the medication-use lexicon and replace them with more appropriate terms.

Background: The medication-use process is often described as consisting of prescribing, transcribing, dispensing, administration, monitoring, and patient education. The term “transcribing” is a minimization of the highly cognitive process of verification, change, and transformation from an ordered to a dispensable and administrable therapy. A more descriptive term is needed, such as “perfecting” and “perfecting.”

5. Frank Sosnowski (NY), Mike Blumenfeld (NY), Debra Feinberg (NY), Tom Lombardi (NY), and Leigh Briscoe-Dwyer (NY): Guidelines for Remote Verification of Medication Orders

Recommendation: ASHP should develop guidelines and standards for a safe and effective process for remote verification of electronic medication orders that include recommendations on interstate, intrastate, and international remote order verification.

Background: The growth of remote order-entry technology, combined with the shortage of pharmacists and budgetary constraints, has resulted in an increase in the consideration of remote order entry (off-site) order verification. There are currently no standards of practice for remote and off-site order entry nor are there guidelines for selection of contracted providers of this resource.

6. Michael W. Kelly (IA), Kelly M. Smith (KY), Ted L. Rice (PA), Marie A. Chisholm-Burns (AZ), Erin R. Fox (UT), and Daniel Hays (NY): Clinical Pharmacist’s Role in the Emergency Department
Recommendation: ASHP should develop a document that describes the clinical specialist’s roles, responsibilities, and qualifications for practice in the emergency department.

Background: Practice sites have been developing quickly over the past 4-5 years. Many questions appear on ASHP listservs about justifying services, qualifications of individuals, and job descriptions in this area of practice. An ASHP document could be used by practitioners as a standard for the qualifications, roles, and responsibilities of specialty pharmacy practitioners in the emergency department.

7. Judy Schneider (MN): Review of ASHP Policy 0404

Recommendation: The appropriate ASHP council should review ASHP Policy 0404 (“Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient Assistance Programs”) and consider revising it to advocate for one standardized application form.

Background: Drug company assistance program forms are still radically different and time-consuming to complete. The average citizen cannot navigate the process and the forms on their own. ASHP made a strong step in the right direction with this policy but not enough has been done continue to move this item forward since the policy was adopted. It is great to have ASHP Policy 0404, but ASHP needs to do more than have a good policy on the books – ASHP needs to work to make it happen.

Recommendations by Delegates on Tuesday, June 10:

1. Giselle Rivera (PR): Availability of Medication Guidelines in Other Languages

Recommendation: ASHP should advocate that FDA and manufacturers publish medication guidelines in languages other than English for use in areas with significant populations of non-English-speaking patients.

Background: FDA requires pharmacists to distribute medication guidelines when dispensing certain medications. Because these medication guidelines are available only in English, they are of limited value to non-English-speaking patients. FDA has suggested that practitioners individually request that manufacturers provide medication guidelines in other languages. ASHP should encourage FDA and manufacturers to develop medication guidelines in other languages.

2. Elaine Huang (WA), Dan Crona (CO), Meghan Davlin (OH), Carrie Jacobs (IN), and Kate Palmer (IA): Developing Mentoring Relationships

Recommendation: ASHP should explore development of a set of tools for pharmacists and students to develop skills that build mentoring relationships to foster a more prepared and professional health-system workforce.

Background: ASHP Policies 0110 (Professional Socialization) and 0509 (Developing Leadership and Management Competencies) and the MentorExchange program have created a foundation for mentorship. The Student Forum Executive Committee (SFEC) feels that as ASHP continues to strengthen the relationships among ASHP, state affiliates, and student societies, creating these tools will further enhance these relationships while fostering student interest in health-system pharmacy careers.

3. Thomas J. Johnson (SD): Use of Terms "Resident" and "Residency"

Recommendation: ASHP should monitor actions of medical organizations in regards to the definition of terms used to describe postgraduate training for pharmacists (i.e., "resident" and "residency").

Background: The American Medical Association has a resolution before its House of Delegates that would restrict use of the terms “resident” and “residency” to physicians. Pharmacists have a long history of postgraduate training in residency programs. Efforts to limit use of these terms to specific professions need to be monitored closely, and ASHP should take action when necessary.

4. Erin Hendrick (CO): Implementing Recommendations of Center for Health-System Pharmacy Leadership’s Student and New Practitioner Leadership Task Force Report

Recommendation: ASHP should assertively implement the recommendations outlined in Leadership: Not an Option but a Professional Obligation, the report of the Center for Health-System Pharmacy Leadership’s Student and New Practitioner Leadership Task Force.

Background: The report outlines eight recommendations to cultivate leadership skills among pharmacy students and new practitioners, starting with the fundamental point that we should promote leadership as a professional obligation among all pharmacists.
5. Dennis Williams (NC): Standardized Concentrations for Parenteral Nutrition Solutions

Recommendation: ASHP should consider developing a policy about the relative benefits of standardizing parenteral nutrition concentrations.

Background: The Board of Directors of the American Society for Parenteral and Enteral Nutrition (ASPEN) has sent a letter to ASHP that suggests there is no evidence of safety or economic benefits of standardizing parenteral nutrition concentrations for all patients in general. ASHP has policy about standardized drug concentrations in continuous infusions, but has no policy regarding standardization of parenteral nutrition concentrations.

6. Lourdes Cuellar (TX): Guidelines for Affiliation Agreements Between Hospitals and Colleges of Pharmacy for Faculty Placement within Health Care Institutions

Recommendation: ASHP should develop guidelines to assist pharmacy directors in initiating and maintaining agreements with colleges of pharmacy regarding faculty placement within their health care systems that maximize value to the health system, the pharmacy department, and the college of pharmacy.

Background: There are currently a plethora of models for affiliation agreements for faculty placement within health care institutions, many of which provide little return on investment for the health care system. Faculty often work without any collaboration with the department of pharmacy, and there is no hand-off regarding care of patients they may be following. ASHP should develop guidelines for such affiliation agreements that would address equitable return for the pharmacy department, the health system, the college of pharmacy, and students.

7. Deb Saine (VA): Use of Smart Infusion Pumps

Recommendation: ASHP should develop a policy encouraging health systems to implement use of smart infusion pumps to enhance patient safety and defining the pharmacist’s role in use of this technology.

Background: A smart infusion pump utilizes a defined medication library, employs hard and soft stops for minimum and maximum dosage limits, and provides quality improvement data. Health systems should be encouraged to implement use of smart pumps as safety initiatives and/or as replacements for pumps that do not provide infusion safeguards. Pharmacists should be involved in evaluating and implementing this technology as well as in building and maintaining medication libraries.

8. Kristina De Los Santos (AZ), Dianne Wright (AZ), Larry Anderson (AZ), Ernie Dole (AZ), Joe Anderson (NM), Melanie Dodd (NM), and Dennis Williams (NC): ASHP Leadership in the Development of Requirements Beyond Licensure for Pharmacists in Advanced Patient Care Roles

Recommendation: ASHP should assume a leadership role in developing standards for requirements beyond licensure (e.g., the pharmacy profession’s presently recognized training and certifications) for pharmacists in advanced patient care roles.

Background: ASHP’s leadership agenda supports provider status for pharmacists. To accomplish this goal, ASHP should provide guidance to states regarding requirements beyond licensure for those who assume advanced patient care roles. Uniform requirements beyond licensure (e.g., presently recognized training and certifications) amongst states is necessary to move the profession forward in a cohesive manner and ensure the quality of patient care.

9. Lindsey R. Kelley (MN): Extending Resident Member Benefits to Fellows

Recommendation: ASHP should explore extending to fellows the same dues levels, membership benefits, and categorization as resident members.

Background: ASHP members completing fellowships are not currently extended any unique dues levels or benefits. The New Practitioner Forum Executive Committee feels that extending to fellows the same dues levels and benefits that residents currently enjoy is in line with ASHP’s stance on postgraduate training and would exhibit to fellows appreciation of their membership and involvement in the organization.

10. Kristy Butler (OR), and the delegations from Arizona, New Mexico, North Carolina, and Oregon: ASHP Support for H.R. 5780, “Medicare Clinical Pharmacist Practitioner Services Coverage Act of 2008”


Background: This bill would provide federal recognition of pharmacists as providers under Medicare Part B and ASHP support would be consistent with the ASHP vision and the current and future leadership agendas.
11. Dale English II (OH), Kathy Donley (OH), Karen Kier (OH), Peg Huwer (OH), and Doug Stillwell (OH): 2020 Residency Planning

**Recommendation:** ASHP should work with other interested parties and key stakeholders to develop a strategic plan to achieve the 2020 residency requirement for all new graduates advocated in ASHP Policy 0701.

**Background:** The Ohio Society of Health-System Pharmacists House of Delegates chose not to currently endorse the 2020 residency requirement for all new graduates after listening to a report from Kathy Knapp that attaining such a requirement is virtually impossible. We believe that it is vital that work be done to give the profession an outline for attainment of this requirement.

12. William Yee (CA): Professional Status of Pharmacists and Residents

**Recommendation:** ASHP should develop a policy that advocates that all states recognize pharmacists and pharmacy residents practicing in hospitals and health systems as professionals and therefore exempt employees under labor laws.

**Background:** Pharmacists in California are not recognized as professionals under state labor laws and are subject to hourly pay, mandated lunches and breaks, and overtime. This law has been the subject of discussion to be extended to pharmacy residents. This extension may have a negative impact in the finances and ability to train residents in California.

13. Michael McEvey (IL), Todd Karpinski (IL), Scott Meyers (IL), Andrew Donnelly (IL), Jimmy Dorociak (IL), and Jared Bauer (IL): Proper Disposal of Expired and Unusable Pharmaceuticals

**Recommendation:** ASHP should develop best practices for pharmaceutical waste disposal that comply with the Resource Conservation and Recovery Act (RCRA) of 1976 [42 U.S.C. 6901-6992k], with the EPA regulations on pharmaceutical waste in waterways, and with applicable state and federal Department of Transportation requirements for transportation of such waste.

**Background:** A recent series by the Associated Press, actions by the American Pharmaceutical Association, and a recent article in *American Journal of Health-System Pharmacy* all point to renewed interest in this area. RCRA was originally aimed at manufacturing but is increasingly being applied to health care facilities.

Numerous consultants stand ready, for a price, to help pharmacy. We feel that ASHP should develop a set of best practices to guide members who wish to process their pharmaceutical waste without contracting with outside consultants.


**Recommendation:** All ASHP policies should be reviewed to ensure that they support the proper codification of data for automated retrieval.

**Background:** A significant impediment to proper automation of functions is the failure to codify data in a form that is readily and reliably retrievable. ASHP's support of pharmacy automation must include the insistence that all policies enforce the need for proper data codification.

15. Dale English II (OH), Randy Kuiper (MT), Brian Benson (IA), Patricia Knowles (GA), Jennifer Edwards (MT), Tommy Mannino (LA), and Helen Calmes (LA): Ending ASHP Use of Terms "Clinical" and "Staff" To Describe Pharmacists

**Recommendation:** ASHP should eliminate use of the terms “clinical” and “staff” when describing pharmacists.

**Background:** “Clinical pharmacist” is an outdated term, as all pharmacists are now capable of practicing what has been defined as “clinical pharmacy.” Pharmacy is a clinical profession and should be practiced as such, and the expectation should be such from the government, payers, and patients. It is time that we remove our self-imposed labels, come together as a profession, as pharmacists, and provide all patients with the pharmacy services they deserve.

16. Fei Wang (CT), Michael Rubino (CT), and Michael Schlesselman (CT): Safe Disposal of Patient's Home Medications

**Recommendation:** ASHP should take the lead in developing guidelines that describe specific methods to be used for the safe disposal of unused or expired home medications and to actively promote the education of health care professionals, the public, and other stakeholders (e.g., state boards of pharmacy) regarding the safe disposal of such medications.

**Background:** ASHP policy 0614 (Safe Disposal of Patients’ Home Medications) currently does not outline specific details of how to dispose of unused or expired home medications. At present, despite the recommendations of federal guidelines in 2007, it is
still common practice to continue to flush unused or expired medications down the toilet. The major environmental impact of this practice today is provided by numerous examples of these contaminants in our sources of drinking water.


Recommendation: ASHP should develop a policy advocating a requirement for drug manufacturers to disclose the origin of raw materials used in drug products.

Background: The recent heparin shortage has brought to light the importance of knowing the origin of raw material(s) used by drug manufacturers. Even though the heparin example ended up being a manufacturing issue, there was a time during the investigation process in which the source of the raw material was of concern. Currently there is no process to track the safety and origin of the raw materials being used in drug products.


Recommendation: ASHP should collaborate with the Accreditation Council for Pharmacy Education (ACPE) to create objective measures to “actively monitor the long-range impact” of pharmacist training programs as referred to in ASHP policy 0805 (Entry-Level Doctor of Pharmacy Degree).

Background: ASHP should provide guidance to membership regarding which criteria to monitor, how the criteria should be monitored, and what goals must be achieved to successfully meet the criteria regarding the entry-level doctor of pharmacy degree.

19. Scott Takahashi (CA): House of Delegate Chair Elections

Recommendation: ASHP should use audience response technology to expedite the election of the Chair at the House of Delegates.

Background: (No background was provided.)

20. Mark Siska (MA), Jeff Ramirez (MA), and John Poikonen (MA): Equivalence of Telepharmacy and Pharmacist-Present Order/Medication Checking

Recommendation: ASHP should formally promote the use of telepharmacy as a preferred alternative to distributive systems that operate without a pharmacist’s oversight, where telepharmacy is defined as an electronic means by which a pharmacist at a remote location performs the services that would ordinarily be performed by a pharmacist on site.

Background: Telepharmacy applications can permit pharmacists to provide a higher level of service by using imaging and data transmission techniques to allow a remote pharmacist to perform checking as if present and replace night cabinets and other less desirable mechanisms for providing pharmacy services for pharmacies that are not open 24 hours/day, 7 days/week.

21. Mark Siska (MA), Jeff Ramirez (MA), and John Poikonen (MA): Use of Clinical Decision Support to Limit Need for Near-Universal Pharmacist Order Review

Recommendation: ASHP should advocate study of the potential use of clinical decision support in the place of the current practice of near-universal pharmacist order review.

Background: The premise to explore the potential for using automated clinical decision support rather than the current practice of pharmacist review of all medication orders is that pharmacists may be forging higher level clinical participation with need for review of all medication orders that maybe best be done via technology. There may be a subset of drug orders that can safely and effectively be reviewed with technology instead of pharmacists review.

22. Scott A. Meyers (IL), Todd Karpinski (IL), Scott Meyers (IL), Andrew Donnelly (IL), Jim Dorociak (IL), and Jered Bauer (IL): Educational Accreditation Support for ASHP Affiliates

Recommendation: ASHP should evaluate the feasibility of establishing a program to provide educational accreditation services through its ACPE-accredited provider status to support state affiliates in providing high-level education to its members.

Background: Currently many ASHP state affiliates are not accredited by ACPE as a provider of continuing pharmacy education (CPE). Other state affiliates are struggling with the continuously changing and highly demanding criteria related to the provision of CPE. This process should be funded by participating state affiliates on a percent of usage basis calculated and assessed annually. This process would require ASHP to fund the process each year until costs are determined but those costs would be returned to ASHP once the state affiliates were billed.
23. *Mark Siska (MA), Jeff Ramirez (MA), and John Poikonen (MA): Multi-Facility Automation Architecture*

**Recommendation:** The ASHP Section of Pharmacy Informatics and Technology Section Advisory Group on Automation and Documentation strongly encourages pharmacy automation vendors to offer a multi-facility architecture that (1) facilitates centralized medication formulary maintenance, (2) provides efficient methods for entry and update of formulary information, (3) minimizes the possibility of data entry error that could jeopardize patient safety, and (4) supports the reporting of formulary utilization and configuration.

**Background:** Multi-facility healthcare networks are often faced with maintenance of separate, stand-alone formulary and device databases that may be tied to one pharmacy information and automated distribution system or multiple order entry formularies. Generally, each site will manually maintain the formulary for product additions, deletions, descriptions, etc. This model is not only costly from a resource standpoint but also adds risk to patient safety when manually synchronizing between multiple sites.

24. *Tricia Killingsworth (ID) and Caryn Bing (NV): Process for Submission of Interim Recommendations by Delegates*

**Recommendation:** ASHP should develop a process by which delegates can submit recommendations to the Chair of the House between sessions of the House of Delegates.

**Background:** The current ASHP policy process does not facilitate delegate input on urgent issues between sessions of the House of Delegates. ASHP should explore development of a formal process for interim delegate recommendations to the Chair of the House to be addressed and tracked (e.g., heparin shortage due to origin of raw materials).

25. *Mark Siska (MA), Jeff Ramirez (MA), and John Poikonen (MA): Support for Centralization of Distribution Services*

**Recommendation:** ASHP should support the practice of centralizing distributive pharmacy functions, up to and including centralized sterile preparation functions, where such centralization can provide a uniformly higher quality of dose preparation than would be practical at the individual patient care sites served by such centralization.
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2 Sat in Tuesday House Meeting only
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Professional policies approved by the 2008 ASHP House of Delegates

Seattle, WA
June 10, 2008

The new and discontinued professional policies of ASHP are organized here according to the council or other body that initiated or recommended discontinuing them. Policies proposed by councils or other bodies are first considered by the Board of Directors and then acted on by the House of Delegates, which is the ultimate authority for ASHP positions on professional issues. The background information on these policies appears on the ASHP Web site, www.ashp.org; click on “About ASHP,” then on “House of Delegates.” The complete proceedings of the House of Delegates will be sent to delegates and will be posted on the ASHP Web site; a printed copy can be requested from the ASHP Office of Policy, Planning and Communications.

Resolution

Alternative Drug Coding Systems
To encourage federal agencies, the pharmaceutical industry, pharmacy and medical software providers, and purveyors of clinical data repositories and drug databases to explore the potential benefits of supplementing or modifying the National Drug Code with a coding system that can be effectively used across the medication-use continuum.

Executive Committee, Section of Pharmacy Informatics and Technology

ASHP Statement on Bar-Code-Enabled Medication Administration
To approve the ASHP Statement on Bar-Code-Enabled Medication Administration*

Council on Education and Workforce Development

Role of Pharmacy Interns
To advocate for changes in state practice acts and regulations that would define a scope of practice for pharmacy interns that is not limited to that of a pharmacy technician; further,

To explore and promote new staffing models that foster expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

Standardized Pharmacy Technician Training as a Prerequisite for Certification
To advocate that completion of an ASHP-accredited pharmacy technician training program be a prerequisite for the Pharmacy Technician Certification Examination.

Collaboration Regarding Experiential Education
To promote collaboration of health-system teaching sites with the colleges of pharmacy (nationally or regionally), for the purpose of fostering preceptor development, standardization of experiential rotation schedule dates and evaluation tools, and other related matters.

Entry-Level Doctor of Pharmacy Degree
To be an active participant in the Accreditation Council for Pharmacy Education (ACPE) process for the revision of accreditation standards for entry-level education in pharmacy; further,

To actively monitor the long-range impact that the single entry-level degree will have on residency education, availability of experiential training sites, graduate education, and continuing education programs, and the resulting health-system pharmacist applicant pool.

This policy supersedes ASHP policy 9809.
Council on Pharmacy Management

**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.*

**ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems**

To approve the ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems.*

**Health-System Use of Medications and Administration Devices Supplied Directly to Patients**

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

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

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

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

*This policy supersedes ASHP policy 0706.*

**Human Immunodeficiency Virus (HIV) Positive Employees**

(ASHP policy 9201 was discontinued.)

**Council on Pharmacy Practice**

**ASHP Statement on Pharmacy Services to the Emergency Department**

To approve the ASHP Statement on Pharmacy Services to the Emergency Department.*

**ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System**

To approve the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System.*

*This statement supersedes the ASHP Statement on the Pharmacy and Therapeutics Committee dated June 1, 1992, and the ASHP Statement on the Formulary System dated June 7, 1983.*

**Standardization of Intravenous Drug Concentrations**

To develop nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given as continuous infusions; further,

To encourage all hospitals and health systems to use infusion devices that interface with their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities.

**Disclosure of Excipients in Drug Products**

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

(Note: Derivative source means the botanical, animal, or other source from which the excipient is originally derived.)

**Medications Derived from Biologic Sources**

To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of medications derived from biologic sources, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

To facilitate education of pharmacists about the proper use of medications derived from biologic sources.

(Note: Section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] defines biological product as follows: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsenamine or derivative of arsenamine [or any other trivalent organic arsenic compound], applicable to the prevention, treatment, or cure of a disease or condition of human beings.)

*This policy supersedes ASHP policy 0316.*

Council on Public Policy

Education, Prevention, and Enforcement Concerning Workplace Violence

To advocate that federal, state, and local governments recognize the risks and consequences of workplace violence in the pharmacy community and enact appropriate criminal penalties; further,

To collaborate with federal, state, and local law enforcement and other government authorities on methods for early detection and prevention of workplace violence; further,

To encourage all workplace environments to develop and implement a policy for pharmacy personnel that (1) educates about prevention and deterrence of workplace violence, (2) identifies escalating situations that can lead to violence and instructs
employees on protection and self-defense, and (3) provides continued support and care to heal personnel who were directly or indirectly involved in an incident of workplace violence; further,

To encourage the health care community to develop and maintain a communication network to share information about incidents of potential and real workplace violence.

**Regulation of Dietary Supplements**

To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling that includes disclosure of excipients; (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and (4) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met: (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective; (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer; (3) the advertising includes a recommendation to consult with a health care professional before initiating use; (4) any known warnings or precautions regarding dietary supplement–medication interactions or dietary supplement–disease interactions are provided as part of the advertising; and (5) the advertising is educational in nature and includes pharmacists as a source of information.

(Note: Dietary supplement as used in this policy is defined by the Dietary Supplement Health and Education Act of 1994, as amended; 21 U.S.C. 321.)

*This policy supersedes ASHP policy 0718.*

**Appropriate Staffing Levels**

To advocate that pharmacists at each practice site base the site’s pharmacist and technician staffing levels on patient safety considerations, taking into account factors such as (1) acuity of care, (2) breadth of services, (3) historical safety data, and (4) results of research on the relationship between staffing patterns and patient safety; further,

To advocate that regulatory bodies not mandate specific, uniform pharmacy personnel ratios but rather ensure that site-specific staffing levels optimize patient safety; further,

To encourage additional research on the relationship between pharmacy staffing patterns and patient safety.

*This policy supersedes ASHP policy 0717.*

**Medicare Prescription Drug Benefit**

To strongly advocate a fully funded prescription drug program for eligible Medicare beneficiaries that maintains continuity of care and ensures the best use of medications; further,

To advocate that essential requirements in the program include (1) appropriate product reimbursement; (2) affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services, based on a study of those costs; (4) appropriate coverage and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient’s choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

(Note: Fully funded means the federal government will make adequate funds available to fully cover the Medicare program’s share of prescription drug program costs; eligible means the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.)

*This policy supersedes ASHP policy 0721.*

**Federal Review of Anticompetitive Practices by Drug Product Manufacturers**

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

To encourage appropriate federal review of these practices.

*This policy supersedes ASHP policy 0520.*

**Confidentiality of Patient Health Care Information**

To approve the ASHP Statement on Confidentiality of Patient Health Care Information.*

*This statement supersedes a previous version dated June 7, 1999.*

**Uniform State Laws and Regulations Regarding Pharmacy Technicians**

To advocate that pharmacy move toward the following model with respect to technicians as the optimal approach to protecting public
health and safety: (1) development and adoption of uniform state laws and regulations regarding pharmacy technicians; (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy technician certification; and (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to the state board of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

To advocate registration of pharmacy technicians by state boards of pharmacy; further,

To advocate, with respect to certification, as an interim measure until the optimal model is fully implemented, that individuals be required either (1) to have completed an ASHP-accredited program of education and training or (2) to have at least one year of full-time equivalent experience as pharmacy technicians before they are eligible to become certified; further,

To advocate that licensed pharmacists be held accountable for the quality of pharmacy services provided and the actions of pharmacy technicians under their charge.

(Note: Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Registration is the process of making a list or being enrolled in an existing list; registration should be used to help safeguard the public through interstate and intrastate tracking of the technician workforce and preventing individuals with documented problems from serving as pharmacy technicians.)

This policy supersedes ASHP policy 0412.

Council on Therapeutics

ASHP Statement on Criteria for an Intermediate Category of Drug Products

To approve the ASHP Statement on Criteria for an Intermediate Category of Drug Products.*

Pharmacist’s Leadership Role in Anticoagulation Therapy Management

To advocate that pharmacists provide leadership in the interdisciplinary development, implementation, maintenance, effectiveness monitoring, and assurance of continuity of care of anticoagulation management programs; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients within anticoagulation management programs; further,

To encourage pharmacists who participate in anticoagulation programs to educate patients, caregivers, prescribers, and staff about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, and recommended laboratory testing and other monitoring.

Generic Substitution of Narrow Therapeutic Index Drugs

To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

To oppose a blanket restriction on generic substitution for any medication or medication class without evidence from well-designed, independent studies that demonstrate inferior efficacy or safety of the generic drug product.

Dietary Supplements Containing Ephedrine Alkaloids

(ASHP policy 0302 was discontinued.)

Inaugural address of the President-elect

Pharmacy’s tipping point: Finding our way to the future

KEVIN J. COLGAN

It is truly a great honor for me to be your president. It is a privilege that very few have the opportunity to experience. For that reason, from the very bottom of my heart, I thank you for electing me to serve you, ASHP, and, most importantly, our profession.

As you can imagine, after I was informed about the election results, I immediately called my wife, Mary Kay, whom many of you know is also an ASHP member and a home care pharmacist. The first words out of her mouth were, “So, Kevin, what are we going to do now?”

I have been thinking about that question for almost nine months. I think the best way to start is to acknowledge my wonderful family, the source of my strength and my joy: my wife Mary Kay, my companion and love for life; my daughter Christina; my two sons Brian and John; and my daughter-in-law, Andrea. You are truly the best a husband and father could ever ask for.

There are a couple of other “families” I want to acknowledge as well, especially my coworkers and partners at EPI-Q, with special thanks to our president, Mark Jewell, for his unending support.

Many thanks to my board buddy and very special friend Janet Silvester, who has simply been one of the best ASHP presidents ever.

Thanks to my Elmhurst Memorial Hospital family, where I spent 16 years of my career, and especially to Gail Bernstein for being my sounding board.

And, of course, the rest of the ASHP family, including

- The ASHP Board of Directors, who are one of the brightest and most caring group of individuals I know, especially very special friends from past boards Roland Patry, Marjorie Phillips, Bill Puckett, Bonnie Senst, Brian Erstad, Agatha Nolen, and Marianne Ivey,
- The past presidents whose leadership I have been so fortunate to observe, especially Steve Scheaffer, Deb Devereaux, Dan Ashby, my special friend T. Mark Woods, Jill Martin-Bone, and my mentor Cindi Brennan,
- The individuals who keep ASHP on top, including Henri Manasse, Bill Zellmer, and the rest of the ASHP staff, especially Kathy Biesecker, Ellen Wilcox, and Aretha Hankinson,
- My friends from the Illinois Council of Health-System Pharmacists, especially Scott Meyers and Trish Wegner, and

Presented at the ASHP Summer Meeting, Seattle, WA, June 10, 2008.

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The following ASHP Reports and information on 2008 ASHP award recipients appear in the online version of this issue (www.ajhp.org):

- "Thinking Seven Miles Out": remarks of ASHP Executive Vice President and Chief Executive Officer Henri Manasse, Jr., Ph.D., Sc.D.
- "Preparing for the Profession Ahead": remarks of outgoing ASHP president Janet Silvester, M.B.A., FASHP
- "Putting Resources to Work for Strategic Benefit": 2008 Report of the Treasurer by ASHP Treasurer Paul W. Abramowitz
- ASHP Board of Directors, 2008–2009
- Professional Policies approved by the 2008 ASHP House of Delegates
- ASHP Board of Directors Award of Honor
- ASHP Award of Excellence
- ASHP Honorary Membership
- ASHP Annual Report

To read more about 2008 Society activities, go to www.ashp.org/s_ashp/docs/files/ASHP_AnnualReport07.pdf

- Nicole Allcock and Elaine Ladd, two young pharmacists and very special friends who personify a new breed of practitioner.

Many of you who know me have seen both the professional and the fun side of me, but only a few of you have seen the spiritual side, which is also a part of who I am. For that reason, I would like to offer a prayer as I begin my remarks today.

Eternal Father, I offer you the profession of pharmacy. Our professors, mentors, and peers have given each of us the knowledge we need to help patients make the best use of their medications. I beseech you to give us the spirit, resources, and conviction we need as individual pharmacists and technicians to uphold our calling to comfort, treat, and, when possible, to cure the ill. But most of all, I ask you to create a stir in the heart of pharmacy to act as your agents of help for the sick and suffering. Amen.

A profound time of change

Today, I would like to talk to you about the core values of our profession, and what I believe will be the future of pharmacy.

Let's start by looking at a little history. The city in which we're meeting this week has known distinct, historical eras of change. From the lumber industry era, to the era of the Klondike gold rush, to the city's great shipbuilding days, to the dominance of Microsoft in the business climate of both this city and nation... each era has profoundly changed Seattle and changed our world.

Likewise, pharmacy has seen many eras of change, beginning with the first apothecaries of more than five centuries ago to today's modern era of pharmaceutical research and discovery. Although this era is still unfolding, it is also marked by profound change. This change will be driven by the "triple imperatives" of health care: the cost of care, the quality of care, and our ability to provide access to care.

Everywhere we look, we can see the need for change.

We see it in costs. The United States can no longer compete in a global economy where health care consumes 18% of our gross domestic product when no other industrialized country is over 13%. Our Medicare structural deficit is growing, our population is aging, costs are rising, and, sadly, 7 out of 10 people who need health insurance say they have difficulty affording it.

We see it in quality. We all know that quality is highly variable in our nation. Barely half of our patients are treated according to evidence-based guidelines. Let me give you an example: When my colleagues and I researched the state of anticoagulation therapy for a series of articles in 2005, we found massive underutilization of warfarin in eligible patients. That's just one series of studies, but it illustrates how far we have to go in using evidence-based medicine even with a medication that's been around for 50 years.

And finally, we see it in access. In this election year, all of the Presidential candidates seem to recognize the travesty of having 48 million uninsured citizens. Although they each have different approaches, all of the candidates recognize that this situation must change.

A perfect example of lack of access is the story of the owner of my local dry cleaners. She and I often talk, and she knows I'm a pharmacist. Every time she's sick, she asks me for advice and tells me she can't afford health insurance as a small business owner. The effect of having no insurance reached a critical point last year when she experienced a catastrophic burn that required skin grafting. She shared with me how she was struggling to pay for her health care.

No citizen should have to go through what she has been going through. Health care is an essential component of a great society—a society that can care for children, the elderly, the paralyzed, and even those small business owners and their employees who are just getting by.
Reaching critical mass

I believe that the climate for change is so significant that we actually have reached a “tipping point.” The phrase “tipping point” means “the moment of critical mass, the threshold, the boiling point...”. For pharmacy, the tipping point lies somewhere between a remarkable past and a very uncertain future. In the months and years ahead, we could move into a new era in which pharmacists are critical components of every health care team... or we could become marginalized.

It could go either way.

It all depends upon how the value of our efforts is perceived by others. I believe that society will ultimately decide to address the triple demands of cost, quality, and access, as a matter of value.

I think there’s no doubt that the nation’s employers, our elected officials, our patients, and other institutions will begin to vigorously challenge the value of what we, as pharmacists, do, and what our fellow health care colleagues do. Frankly, we should be challenged. We need to show that we can improve quality and, in doing so, reduce costs. We need to show our value to employers who have difficulty competing globally. We need to demonstrate value to a government pressured by a population that is growing older and consuming more and more health care resources.

So, how will we as pharmacists demonstrate our value?

Well, first of all, we need to demonstrate the vital role that pharmacists play by ensuring that patients not only have the right medications, but the best medication plan.

Secondly, we need to demonstrate that we improve the safety of medication use.

Third, we need to show that we improve overall patient outcomes.

In addition, we need to show that we can make health care more efficient. I’m not talking about efficiency only in the context of saving money. I mean being more efficient with our resources so we can care for more patients. We need to demonstrate the value of our expertise in treating chronic illness—the true core of health care spending.

What are the barriers?

But it’s clear that achieving these goals is not an easy task in today’s environment. There are significant barriers in our way. In getting ready for this meeting, I talked to pharmacists across the country. I wanted to hear about the barriers and frustrations they face each day. And I heard some familiar refrains:

- I heard from Henry Bussey at the University of Texas at Austin that its clinic today cannot afford to hire another pharmacist, but it has been able to hire five nurse practitioners and physician assistants who can bill three to four times what Henry can bill.
- I attended a hospital staff meeting and heard the manager say that the pharmacy could do more if it had more resources. The staff echoed that they were underutilized in selecting the best treatments for patients, not because the medical staff or anyone else in the institution questions their ability but because they don’t have adequate resources to free their pharmacists to do more.
- I met with a new practitioner group, all residency-trained practitioners, and heard the concerns of Jennifer Ellison, from St. Francis Medical Center in Peoria, Illinois, about direct patient care. She questioned the credentials that should be required and relayed a story about an extraordinary pharmacist at St. Francis who actively provides direct patient care to the bariatric surgery patients. This pharmacist does not have residency training or any other advanced credentials but still provides excellent one-on-one care. Her question was, “How will pharmacists who haven’t done residencies or who don’t have BPS certification qualify for these positions?”
- A new practitioner who now works at Abbott Laboratories said she left clinical practice because she was frustrated with her legal ability to take responsibility for patient outcomes.

So, with all of these challenges, why do most of these same pharmacists stay in practice? Fortunately, there are many, many reasons.

Pharmacists told me that they are motivated by being able to interact with patients and collaborate with physicians and nurses. They get excited about opportunities to teach diabetic and asthma patients about their medications. They feel empowered by their ability to guide their hospital’s vaccination program and improve the overall health of their community.

Others tell how they have been directly involved in implementing smart pumps and creating medication screening programs for surgical patients.

I’ve heard from directors who are proud of their ability to build programs that bring tremendous value to their organizations. A pharmacy director told me that although his labor costs are sky high, he has been able to keep overall costs very low because of the value of the clinical services his pharmacists provide.

But perhaps the staff at Detroit Receiving summed it up best by saying they are motivated by being held responsible for individual patient outcomes.

Transformational change

Clearly, there is a big disconnect between our own sense of value and many of the real-world situations in which we actually find ourselves. We can try to strip away the inefficiencies and enhance the way we practice—and we should—but the challenges are great and many.

We must attack these challenges head-on. But in order to be success-
ful, in order to fully demonstrate our value, we must first reaffirm our commitment to those beliefs that brought us to this profession in the first place.

I’m talking about reaffirming our commitment to our “calling” as pharmacists... the calling that obliges us to do whatever we can to ensure that our patients receive the best care possible.

Why is it so important for us to renew this commitment? Think of it this way: Planning and managing patient medication regimens is our niche—it’s our strong suit.

We need to embrace it, claim it as our own, and do it better than it has ever been done before.

But in order to plan and manage medication regimens in a meaningful way, we need to first make sure that every newly diagnosed patient with a chronic condition and every patient who is taking multiple medications is seen by a pharmacist. And we need to make sure that every patient in every hospital is seen every day by a pharmacist: every patient, every day.

My good friend Marianne Billeter from Ochsner Health System in New Orleans is a great example of just how this is possible. Marianne’s pharmacy attempts to see patients every day, either by attending physician rounds or by providing pharmaceutical consultation at the bedside. Clinical specialists participate on all major services, and they strive to ensure that a patient’s medication regimen coincides with the most recent treatment guidelines for that disease. This team truly feels accountable for ensuring that patients receive the very best drug therapy.

Now, you may be sitting there thinking that your situation isn’t like Ochsner’s. You may assume that Ochsner is a big urban teaching hospital with unlimited resources. But it doesn’t have unlimited resources. There are only 40 pharmacists for 500 beds.

How can we mirror Ochsner’s success? We need to approach our challenges like they do: We need to advocate for our profession, and we need to demonstrate our value. When a pharmacist is involved, everyone moves a step closer to offering the best care possible. That is our calling, and when we follow it, we are able to improve patient care and advance the stature of our profession.

Following our calling

As pharmacists, we are also called to improve medication safety. Earlier this year, USA Today reported the tragic story of Emily, a two-year-old who had a curable abdominal tumor but was given an incorrect chemotherapy i.v. admixture and died. The technician who prepared the i.v. was reportedly on the Internet planning her wedding just before mixing the dose. And the pharmacist overseeing the technician’s work missed the error.

I believe that developing a culture of safety is the single most important factor in improving medication safety. But pharmacists must do more than demonstrate our own commitment to safety. We need to embrace our role as educators on medication safety for technicians, physicians, nurses, patients, and their caregivers.

Yes, it takes courage to “call out” the nurse who borrows another patient’s medication, the anesthesiologist who doesn’t label a syringe, or the coworker who is not competent. It takes time to counsel a patient. It takes effort to specially package a dose so an error does not occur. Nonetheless, pharmacy’s professional culture must be to always do the right thing and to do it right the first time.

Embracing technology is another component of safety. Bar-code scanning of drug administration and the use of smart pumps for i.v. infusions are two key weapons for preventing errors. The use of electronic medical records, electronic prescribing, and robotic dispensing devices are others. These systems are not perfect, but in general they can improve safety.

Our role is clear. Pharmacists must scrutinize these technologies. We must also advocate for their adoption when these technologies demonstrate an ability to improve patient safety. We should play a key role in their implementation, track their impact, and share our experiences with others.

Another key component of safety is the development of performance measures and standards. Not long ago, my colleagues at EPI-Q and I helped convene an expert panel to develop performance measures for bipolar disorder. These measures are vital because 40% of bipolar patients are misdiagnosed with unipolar depression. When treated with selective serotonin-uptake inhibitors, many will experience rapid mood cycling and become even worse. Providers such as the Department of Veterans Affairs, Humana, and Aetna have adopted these new performance measures, and we are already seeing an improvement in the diagnosis and care of bipolar patients across the United States.

We have a similar situation in pharmacy. You may have heard about a new project called the “high-performance pharmacy.” Lee Vermeulen published an article in ASHP’s American Journal of Health-System Pharmacy last year describing more than 70 performance measures for a high-performance pharmacy. He and his coauthors want to develop a strategic approach for improving the medication-use process and, ultimately, for improving quality and safety. Professionwide acceptance of performance measures like these and ASHP’s 2015 Health-System Pharmacy Initiative will be instrumental in improving our pharmacy departments and the whole medication enterprise within the health system. But they won’t happen if we don’t push for them! We must follow our calling.
One final thought on patient safety: We must address the issue of competency in our technician work force. Almost all the medication tragedies that have been reported in the media involve technicians in one way or another. It is clear that, at a minimum, our technicians need formal ASHP-accredited training and certification from the Pharmacy Technician Certification Board, no matter what the setting. Unfortunately, there are only 120 ASHP-accredited training programs for technicians. That's not enough. And so ASHP has made it a priority to tackle technician work-force issues in our collaborative efforts with state affiliates.

But let's not forget: Pharmacists who work closely with technicians know what education and training they need. It is the pharmacist's responsibility to supply that training. We can't allow—we can't afford to allow—technicians to perform tasks for patients that you wouldn't also allow them to perform for a dearly beloved family member.

Our decisions plainly have to be that personal: After all, this is our calling.

As many of you know, I am a former director of pharmacy-turned-researcher. If there is one thing I have learned as a researcher, it is that data drive practice. And, even though we need to vastly grow the amount of research we do, I'm excited by what I see happening in hospitals and health systems that have residency programs. These programs are leading the way in terms of practice-based research. And we need to grow the number of residency programs nationwide and expand this type of research to other sites.

Other efforts also lead to better pharmacy practice and enhanced outcomes. Take postmarketing drug surveillance, for example. In the past few years, there have been significant recalls and warnings for products with broad market penetration. This presents an unparalleled opportunity for pharmacy to take the lead in this area.

As pharmacists, we should also be performing comparative efficacy research and developing large patient registries with monitoring and outcomes data. Until we do this, we will not know which therapy provides the best value and outcome for our patients. Until we do this, we cannot fully demonstrate our value and fulfill our calling.

I maintain that outcomes are affected by everything we do. Therefore, it is our social responsibility as a profession and as practitioners to improve outcomes. In so doing, we will be recognized as change agents in bringing about better health care.

What's next?

There is much to be done. I wouldn't blame you for wondering how you, as an individual pharmacist and as a member of ASHP, can tackle these challenges. But, ladies and gentlemen, "tipping points" occur for a reason. We have an obligation to look inside ourselves, to look at each other, and to work individually and collectively to become champions for change.

Our "calling" is more than just a concept to me. It's very personal.

Seven years ago, I left a job I dearly loved as director of pharmacy at Elmhurst Memorial Hospital. Overall, the hospital provided the resources we needed to build a stellar pharmacy program. But a massive reorganization in the late 1990s brought challenging times and downsizing. Despite hard choices, I was able to hold onto all our pharmacy clinical services. I noticed in the following three years that even though our workload increased over 40%, only departments with new managers were getting additional resources. I believe it was a sincere desire to help make those managers successful and that is not unreasonable.

I also knew that both the medical and administrative staff had high regard for the pharmacy department and were happy with our services. They seemed comfortable with our ability to continue to perform at such a high level, even as I grew increasingly worried that the workload could result in mistakes. I could not get the resources we needed to do the job right, and I knew it. My overworked team was worried, too. They were really stretched to balance their distributive duties with our clinical services. The choices were simple: stay, because it was comfortable and live with the realities and perhaps the consequences of a terrible medication error, or leave and hope that my departure would free up new resources.

I decided to leave a job I really loved, despite the fact that my administrator asked me to stay. And it worked. Within a week, the supervisory staff had convinced our administrator of the problems. That administrator told me that she feared losing them, too, if she didn't respond. So, she approved two new positions. To her credit, it was clear she understood that the pharmacy was at a tipping point.

Anyone who knows me knows what a wrenching decision that was for me. To this day, I get emotional talking about it. But it was a decision that had to be made for the good the pharmacists who worked for me and for the good of the patients under our care. I left because I owed it to these constituents as part of my "calling." And it worked out for me too, because I found another job that I dearly love.

Champions of change

Ladies and gentlemen, transformational change begins inside each and every one of us. So, I leave you today with these challenges:

- Let us be the champions of change.
  We have the history, the stature, the credibility, and the obligation to lead the charge for better health care.
• I urge you to follow your calling at every level of practice, whether you are an inpatient care practitioner, a resident, a clinical specialist, a home care pharmacist, a director of pharmacy, or a community pharmacist working in a chain drugstore.

• And I challenge you to share your calling with your patients. Let them know what to expect from you, their pharmacist. Share your calling with your administrators, other health care professionals, and congressional leaders. Let them know what you stand for. Speak it loudly, and speak it often. It is time for pharmacists to stand up and be heard for what we believe.

However, these challenges cannot be met in a vacuum. We need to work together, as part of the teams within our hospitals and health systems and with ASHP to answer the call for better health care. My friends, the time is now, and the change agents are you and me.
Preparing for the profession ahead


Janet Silvester

Safe medication use is predicated on ensuring that everyone on the pharmacy team works at the same level of excellence.

I'm delighted to be speaking to you as chair of the Board of Directors. One of my greatest obligations is to report to you, the House of Delegates, about the strategic decisions the Board is making for ASHP's future success. We've recently made some significant investments in a number of key areas that we believe will yield tremendous results both for members and for our profession.

One of these investments is our partnership with the ASHP Research and Education Foundation to create the Center on Health-System Pharmacy Leadership. I'm happy to report that 85 pharmacists have enrolled in the Center's inaugural Pharmacy Leadership Academy.

I'm also very pleased to tell you that our investment in creating the new Section on Pharmacy Informatics and Technology has been a resounding success. More than 2300 members have joined the Section and are utilizing the many resources we have developed, including continuing-education opportunities, online resources, and special publishing offerings. And Section leadership is playing a key role in making sure that pharmacists are sitting at the right regulatory and hospital administration tables when decisions are made regarding how technology is used in health systems. For example, the Section recently submitted comments to both the Centers for Medicaid and Medicare Services and the Food and Drug Administration on the issues of electronic prescribing and track-and-trace technologies.

The Board has also made a significant investment in providing the highest-quality, most comprehensive drug information available. When you stop to think about it, drug information—especially the Society's AHFS Drug Information—is at the core of all that we do in pharmacy. It's also at the heart of good patient outcomes and safety. We are taking steps to ensure that ASHP continues to publish the most respected, highest-quality drug information available anywhere. We are also taking steps to ensure that our nation's health policymakers know what constitutes quality drug information and why it's so important to patients and health care providers.

As members of the House, you are intimately connected to the work ASHP is doing to advance pharmacy in hospitals and health systems. You know how committed we are to ensuring that patients receive safe and effective medication therapies. And you believe, as we do, that pharmacists are the health care professionals who can do that best.

We rely on you—pharmacy leaders from all parts of the country and every discipline—to help guide us on public policy positions related to health-system pharmacy practice and safe medication use.

These positions help to support ASHP's new advocacy initiative, which has really taken flight this year. We've focused our resources on

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Remarks presented to the ASHP House of Delegates at the ASHP Summer Meeting, Seattle, WA, June 8, 2008.

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strengthening our relationships with key policymakers in Congress and federal agencies and by working with decision-makers in quality organizations, such as the Joint Commission, the National Quality Forum, and others.

This investment has the ability to bring about real change for our profession, securing our future as key members of the health care team. Specifically, we are focusing on:

- Expanding third-party payment for pharmacists’ drug therapy management services,
- Advocating quality standards that recognize pharmacists’ capabilities,
- Finding additional funding mechanisms for pharmacy residency training,
- Advocating regulatory policies on drug safety that draw on the expertise of health-system pharmacists, and
- Aggressively advocating for nationally standardized technician education and training.

We’ve been hard at work over the past year, solidifying our strategies, ramping up staffing and other resources, and taking on the most pressing issues facing us as a profession. There are many, many activities taking place right now in ASHP’s advocacy arena, but I’d like to focus on three of the most tangible outcomes of this past year.

Pharmacy Technician Initiative

Safe medication use is predicated on ensuring that everyone on the pharmacy team works at the same level of excellence. That includes pharmacy technicians, who are the backbone of much of what we do. Technicians are playing increasingly important roles in our pharmacies, and we need them to take on more if we hope to increase pharmacist’s direct patient care activities.

But technicians can’t take on additional roles and responsibilities without the proper education and training. As you know, ASHP’s position is that pharmacy technicians should complete ASHP-accredited training programs, be certified by the Pharmacy Technician Certification Board, and be registered by state boards of pharmacy. Getting that done won’t happen overnight. And it can only happen with your help.

We are asking all of our state affiliates if they are willing to partner with us on this new alliance. Under the initiative, each affiliate will work with us to assess existing regulations and other factors and harness support from members. ASHP will work with the affiliates to develop an action plan and will offer its support in other ways, including through a new Pharmacy Technician Initiative Resource Center that we’ve launched on ASHP’s website.

And I’m happy to announce that, as of today, the Florida Society of Health-System Pharmacists, the Illinois Council of Health-System Pharmacists, and the Michigan Society of Health-System Pharmacists have already agreed to join with us. Memos of understanding will be signed on Tuesday with these state affiliates, and several other affiliates have expressed strong interest in joining this important campaign.

Stay tuned as we move this effort forward. We’re eager to work with the leaders of each affiliate as we improve the abilities of our pharmacy technician work force.

Research efforts

The second advocacy project I’d like to preview today is focused on research. Good data form the backbone of any advocacy program. We need numbers to tell the story of how pharmacists can make a real difference in patient outcomes and safety when we are involved in medication-use management.

We’ve partnered with the ASHP Research and Education Foundation to award a $65,000 grant for a systematic review of published studies on the outcomes of pharmacist involvement in drug therapy management. We received numerous proposals, and I am pleased to announce today that after an intense review process we have awarded this grant to Dr. Marie A. Chisholm-Burns of the University of Arizona College of Pharmacy. We will use the results of her study to identify gaps in existing evidence and identify questions that need to be answered. And then we’ll raise the money to sponsor research to answer these questions.

ASHP 2015 Health-System Pharmacy Initiative update

Finally, I’d like to report on another: ASHP initiative designed to increase medication safety and effectiveness and boost pharmacists’ role in medication management. The ASHP 2015 Health-System Pharmacy Initiative reached its fifth anniversary this year, and we took the occasion to reevaluate our goals and objectives and make needed changes.

We’ve gotten a lot of feedback over the past five years from hospitals and health systems around the country—as well as state affiliates—that are implementing the initiative. And we used that feedback to refine the objectives, deleting five, adding five, and revising five.

This is a great illustration of the fact that the 2015 Initiative is a living, breathing embodiment of ASHP’s Vision for Health-System Pharmacy Practice. We continue to hear from members who are finding it very helpful in their strategic planning, and we just launched a public recognition campaign to honor those groups and state affiliates that have embraced the Initiative.

Thirteen state affiliates have joined ASHP as 2015 partners. If your affiliate hasn’t done so, I would encourage you to pursue that designation. Be sure to let us know what you’re doing with the 2015 Initiative and how it’s helping you to improve safety and effectiveness in your in-
stitution. We'd like to officially recognize that work.

Conclusion

The Pharmacy Technician Initiative, advocacy research project, and revitalized 2015 Initiative are just three of the many exciting things happening at ASHP on your behalf and on behalf of the pharmacy profession.

I've mentioned the Foundation today in terms of ASHP partnerships, but I think it's also important to remind you that these initiatives can't happen without funding. I will personally hand my gift to Foundation CEO Steve Allen at this meeting. I'm asking everyone here to join me and stop by the Foundation's booth in the exhibit hall to make your gift. Join me in supporting the fabulous work they are doing on behalf of pharmacy.

Lastly, I want to thank each and every one of you for your commitment. Your ideas, assistance, and support provide the foundation for ASHP's continued success. As president, I have a small appreciation for the amount of time that we require of members who become involved. And, as I pass the baton to my good friend Kevin Colgan, I wanted to take a moment and extend my personal thanks and gratitude for all that you do for ASHP.

I can't imagine what my professional—and personal—life would be like without the friends I've made in this wonderful ASHP community over the years. Together, we really do make a great team!
2008 Report of the Executive Vice President and Chief Executive Officer

Thinking seven miles out

HENRI R. MANASSE, JR.

Let me begin this report by extending my personal gratitude to our Board of Directors and to ASHP’s staff for a terrific year. I’m happy to be here and to be talking to you today about some of our future plans.

Thinking strategically, acting deliberately

One of my favorite quotes is by retired National Hockey League player Wayne Gretzky, who said, “I skate to where the puck is going to be, not to where it’s been.” I’d like you to think about that for a moment. It’s a profound statement.

In that same vein, I recently heard from ASHP past-president Dan Ashby about a colleague of his who is in pilot training with the U.S. Air Force. Dan said that pilots are trained not just to see what’s immediately in front of them, but to think seven miles out.

I share that thought because ASHP is not an organization that leaves anything to chance. We think strategically and act deliberately in planning for the future of pharmacy practice in hospitals and health systems, as well as for the efficient and effective internal operation of the organization. We try to think seven miles out.

ASHP thinks strategically and acts deliberately in planning for the future of practice in hospitals and health systems.

ASHP is currently revising its vision for pharmacy practice in hospitals and health systems, and you all have a copy of the Society’s new Leadership Agenda for 2008–2009. Both of these exercises are part of our efforts to influence the future direction of pharmacy practice and patient care. This is an important responsibility, because those of us on the front lines of pharmacy practice tend to worry mostly about the here and now in order to meet the immediate needs of patients. ASHP, in addition to helping its members be successful in their daily work, takes on the key responsibility of thinking long term—we try to think seven miles out.

The importance of vision

Visionary thinking is a hallmark of ASHP. Since its founding in 1942, ASHP’s most influential leaders have used visionary thinking to make the leap from where we were to where we wanted to go. For ASHP, vision means a clear, guiding picture of what we want to achieve. Vision is also a source of inspiration and the substance that binds us together as a group and as an organization.

In the words of John Graham, “If it is big and inspiring enough, a vision—just by being powerfully stated—can set in motion the energy needed for its own achievement.”

ASHP’s vision statement drives our Leadership Agenda. Over the
past several years, we’ve taken a cyclic approach both to revisiting the relevance of items on that agenda as well as the processes by which we’ve traditionally worked collaboratively with the Board and staff to develop it.

In the past few years, we’ve also begun to engage the leadership of the Sections and Forums. And I will say—and I’m sure I reflect the Board’s view here—that this has added immensely to the breadth and depth of understanding “where the puck is going.” We have had a very, very successful interchange with those leaders.

And of course, your involvement here in this House of Delegates and throughout the year is also critical to this process. You help us think from the frontlines, giving us insight into the here and now that must be considered as we contemplate the future. Of course, we also count on you to accept and advance ASHP’s professional policies, which strengthen, broaden, and ensure the relevance of the work we do for patients.

The importance of strategic planning

In ASHP’s strategic exercise this year, we called together our Board, our Section and Forum leadership, and key staff members from throughout the organization. We started by assessing the professional challenges and opportunities that pharmacy practice will encounter over the next five years. This was a very robust discussion due to the conditions in which we find ourselves. I can’t recall in my lifetime—and I’m sure many of you will concur with me—that there has ever been a health care system in so much turbulence.

We then looked at the implication of the challenges that we identified. More specifically, we looked for the opportunities within these challenges. Based on the themes that were teased out and developed from that exercise, we devised ASHP’s 2008–2009 Leadership Agenda (www.ashp.org/s_ashp/doc1.c.asp?CID=219&DID=256).

This agenda, which the Board recently approved, is a vital, living document. I hope you’ll take time to read it. But more importantly, I’d like you to take it back home with you, discuss it with your fellow members of ASHP affiliated state societies, talk about it in your workplace, share it with your boss…after all, this agenda is ASHP’s guiding light.

The first Leadership Agenda item calls on the Society to help improve the quality of medication use in hospitals and health systems. This is our core responsibility as pharmacists—the safe and effective use of medicinal agents, vaccines, biologicals, and contrast media.

The second agenda item calls for us to foster optimal models for the deployment of pharmacy resources in hospitals and health systems. There clearly are limits on both the financial and personnel resources we have in our workplaces. The challenge for all pharmacy departments is to deploy those resources efficiently and effectively to achieve good patient outcomes.

The third item ensures that the pharmacy workforce in hospitals and health systems has the capacity to meet current and future patient needs.

The fourth agenda item calls on ASHP to cultivate the leadership skills of health-system pharmacists. ASHP continues both to invest financially in this priority and develop programs related to leadership development.

ASHP’s Leadership Agenda is a dynamic piece of both our strategic thinking and daily work. The agenda itemizes key priorities for our staff to focus on over the next year. It drives our internal decisions, influencing the types of articles we choose to publish in our clinical journal, how we direct our public relations efforts, what the primary issues in advocacy are, and so on.

Lastly, the Leadership Agenda informs ASHP’s continuing dialogue with a variety of quality and safety organizations, policymakers, and fellow health care professionals in medicine and nursing.

A vibrant, inspiring community

Let me conclude by pledging to you that ASHP will always focus on helping members in all aspects of pharmacy practice in hospitals and health systems achieve their professional goals and aspirations. We also pledge to provide you with a vibrant and inspiring community of pharmacy practitioners, whether you’re participating with us electronically, visiting our offices for a variety of policy or planning meetings, or just talking with your colleagues. We also pledge to push the envelope of pharmacy practice, making it safer for patients and fulfilling the needs, interests, and hopes of our members, especially our young people.

Finally, we pledge to you that we will stay focused on the issues you face today and the challenges awaiting you tomorrow. Let’s continue to look seven miles out.

Reference

2008 Report of the ASHP Treasurer

Putting resources to work for strategic benefit

P A U L W. A B R A M O W I T Z

The Society’s financial year is June 1 through May 31, coinciding with the Society’s policy development year. Because the fiscal year ends May 31, the Treasurer has three financial periods to cover in the annual report: (1) final audited prior-year numbers (for the fiscal year 2007), (2) current year (2008) projected performance, and (3) the budget for the fiscal year ending May 31, 2009.

The audit of the May 31, 2007, financial statements of the Society and the Society’s subsidiary, the 7272 Wisconsin Building Corp., resulted in an unqualified opinion. Copies of the audited statements can be obtained by contacting the ASHP Executive Office.

Fiscal Year Ended May 31, 2007—Actual

Last year, Treasurer Marianne Ivey reported to you that the Society was expecting a $3.171 million surplus for the 2007 fiscal year. We actually ended the year with a $5.645 million surplus: $161,000 from core operations, $5.564 million from the program development budget, less $80,000 (net) spending on programs approved to be funded from net worth (Figure 1). The strong finish in our long-term investment portfolio (17%+ for the year) accounted for 78% of the difference between our actual and forecasted year-end results. With the $5.645 million surplus, the Society’s net worth increased to $47.352 million (Figure 2) or 96% of total ASHP and 7272 expense. Our policy is to maintain net worth at 75% of total ASHP and 7272 expense (the expense of the Society’s wholly owned subsidiary, the 7272 Wisconsin Building Corp.) (Figure 3), with a ceiling of 90% and a floor of 60%.

The Society’s May 31, 2007, year-end balance sheet was as impressive as the statement of revenue and expense (Figure 2). Assets increased by $11.228 million, compared with a $5.582 million increase in liabilities. The asset-to-liability ratio, which had been 4.18:$1.00 at May 31, 2006, fell slightly to a still very healthy 3.53:$1.00 at May 31, 2007.

Fiscal Year Ended May 31, 2008—Projected

This year’s financial performance (as of January 2008) is projected to exceed budget in the core but fall short in the program development budget (funded by investment income) because of sagging performance in the stock market. A $182,767 surplus in the core (a $993,000 deficit was budgeted) and a $2,077 million deficit in the program development budget are expected
(Figure 1). Spending from net worth is projected at $884,433. If we achieve these year-end projections, the Society’s net worth at May 31, 2008, will be $44.574 million, 86% of total ASHP and 7272 expense.

**Fiscal Year Ending May 31, 2009—Budget**

The Society’s 2009 budget reflects the Board’s commitment to expanding membership services while continuing to fund new products and services and support the Society’s infrastructure. For the fourth consecutive year, expenses in the Society’s core budget exceed revenue (Figure 1). However, rather than cut programs to produce a balanced core budget, the Board again chose to use excess investment income from the program development budget to fund the anticipated gap between revenue and expenses. Adding the budgeted core deficit to the surplus budgeted in the program development budget produces a corporate-wide balanced budget, before spending from net worth.

**Programs Funded from Net Worth**

Taking advantage of the Society’s strong financial condition, the Board of Directors has funded three programs from accumulated net worth. These commitments will (1) ensure the currency and competitiveness of ASHP’s drug information product line, (2) fund initial operations of the Center for Health-System Pharmacy Leadership, which is a joint initiative of ASHP and the ASHP Research and Education Foundation, and (3) enhance ASHP’s advocacy of its professional policies before quality-improvement organizations (such as the Joint Commission) and governmental agencies. The Board is confident that the three-year cost of these initiatives—nearly $5 million—will yield important strategic benefits for the Society and its members. At the conclusion of funding these programs, the Society’s net worth will still be in excess of 70% of total ASHP and 7272 expense. The Board is studying how to fund these three initiatives on a continuing basis.

**Conclusion**

In my first report as ASHP Treasurer, I’m extremely pleased to tell you that the Society is a strong and vibrant organization from both a membership and a financial viewpoint. As I complete my first year as your Treasurer, I can tell you that I am also pleased to have joined a Board that does not hesitate to commit the resources of the Society to advancing and supporting the professional practice of pharmacists. An excellent example of this is the Board’s funding of ASHP’s enhanced advocacy program, which we expect to yield immense returns in the implementation of the professional policies approved by this House. I am proud to be your Treasurer, and I look forward to serving you in the years ahead.

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<tr>
<th></th>
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<tbody>
<tr>
<td>Gross revenue</td>
<td>$41,452</td>
<td>$40,928</td>
<td>$42,901</td>
<td>$43,311</td>
</tr>
<tr>
<td>Operating expense</td>
<td>(42,116)</td>
<td>(42,604)</td>
<td>(43,341)</td>
<td>(45,602)</td>
</tr>
<tr>
<td>Operating Income</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>$271</td>
<td>$300</td>
<td>$300</td>
<td>$300</td>
</tr>
<tr>
<td>Other expense</td>
<td>(437)</td>
<td>(290)</td>
<td>(350)</td>
<td>(291)</td>
</tr>
<tr>
<td>Earnings from subsidiary</td>
<td>1,401</td>
<td>1,150</td>
<td>1,150</td>
<td>1,161</td>
</tr>
<tr>
<td>Investment income subsidy</td>
<td>132</td>
<td>123</td>
<td>123</td>
<td>123</td>
</tr>
<tr>
<td>Core Net Income</td>
<td>$161</td>
<td>$(993)</td>
<td>$183</td>
<td>$(1,598)</td>
</tr>
</tbody>
</table>

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<th></th>
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<th></th>
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<tbody>
<tr>
<td>Investment income</td>
<td>$7,688</td>
<td>$3,896</td>
<td>$702</td>
<td>$4,141</td>
</tr>
<tr>
<td>Program expenses</td>
<td>(2,124)</td>
<td>(2,903)</td>
<td>(2,779)</td>
<td>(2,543)</td>
</tr>
<tr>
<td>PD Net Income</td>
<td>$5,564</td>
<td>$993</td>
<td>$(2,077)</td>
<td>$1,598</td>
</tr>
</tbody>
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<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Net program spending</td>
<td>$(80)</td>
<td>$(884)</td>
<td>$(616)</td>
</tr>
<tr>
<td>ASHP Net Income</td>
<td>$5,645</td>
<td>$  -</td>
<td>$2,778</td>
</tr>
</tbody>
</table>
Figure 2. ASHP statement of financial position (in thousands).

<table>
<thead>
<tr>
<th></th>
<th>Actual as of May 31, 2006</th>
<th>Actual as of May 31, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets</td>
<td>$ 4,792</td>
<td>$ 7,060</td>
</tr>
<tr>
<td>Fixed assets</td>
<td>$ 1,388</td>
<td>$ 2,652</td>
</tr>
<tr>
<td>Long-term investments-at market</td>
<td>$ 43,900</td>
<td>$ 49,563</td>
</tr>
<tr>
<td>Investment in subsidiary</td>
<td>$ 3,144</td>
<td>$ 2,853</td>
</tr>
<tr>
<td>Other assets</td>
<td>$ 1,586</td>
<td>$ 3,912</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td>$ 54,812</td>
<td>$ 66,040</td>
</tr>
<tr>
<td><strong>LIABILITIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current liabilities</td>
<td>$ 12,587</td>
<td>$ 18,228</td>
</tr>
<tr>
<td>Long-term liabilities</td>
<td>$ 519</td>
<td>$ 460</td>
</tr>
<tr>
<td><strong>Total Liabilities</strong></td>
<td>$ 13,106</td>
<td>$ 18,688</td>
</tr>
<tr>
<td><strong>NET ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net assets</td>
<td>$ 41,706</td>
<td>$ 47,352</td>
</tr>
<tr>
<td><strong>Total Net Assets</strong></td>
<td>$ 41,706</td>
<td>$ 47,352</td>
</tr>
<tr>
<td>Total Liabilities and Net Assets</td>
<td>$ 54,812</td>
<td>$ 66,040</td>
</tr>
</tbody>
</table>

Figure 3. 7272 Wisconsin Building Corp. (ASHP subsidiary) statement of financial position and statement of activities for fiscal year 2007 (in thousands).

<table>
<thead>
<tr>
<th></th>
<th>Actual as of May 31, 2007</th>
<th>Fiscal Year Ended May 31, 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets</td>
<td>$ 1,319</td>
<td>Gross revenue $ 6,129</td>
</tr>
<tr>
<td>Property and plant (net)</td>
<td>$ 18,937</td>
<td>Operating expense (4,141)</td>
</tr>
<tr>
<td>Other assets</td>
<td>$ 1,639</td>
<td>Operating Income $ 1,988</td>
</tr>
<tr>
<td><strong>Total Assets</strong></td>
<td>$ 21,895</td>
<td>Provision for income taxes $ (587)</td>
</tr>
<tr>
<td><strong>LIABILITIES</strong></td>
<td></td>
<td>Increase in Net Assets $ 1,401</td>
</tr>
<tr>
<td>Current liabilities</td>
<td>$ 663</td>
<td>Owner’s distribution and capital contributions $ (1,692)</td>
</tr>
<tr>
<td>Mortgage payable</td>
<td>$ 17,992</td>
<td>Net Increase in Net Assets (291)</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>$ 387</td>
<td></td>
</tr>
<tr>
<td><strong>Total Liabilities</strong></td>
<td>$ 19,042</td>
<td></td>
</tr>
<tr>
<td><strong>NET ASSETS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net assets</td>
<td>$ 2,853</td>
<td></td>
</tr>
<tr>
<td><strong>Total Net Assets</strong></td>
<td>$ 2,853</td>
<td></td>
</tr>
<tr>
<td>Total Liabilities and Net Assets</td>
<td>$ 21,895</td>
<td></td>
</tr>
</tbody>
</table>
Board of Directors Reports on Councils

ASHP councils met in Bethesda, Maryland, September 25–26, 2007.

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.

Other Council Activity: Additional subjects the council discussed, including issues for which it has begun to develop policy recommendations.

Policy Recommendations

1 Council on Education and Workforce Development
   A. Hole of Pharmacy Interns
   B. Standardized Pharmacy Technician Training as a Prerequisite for Certification
   C. Collaboration Regarding Experiential Education
   D. Entry-Level Doctor of Pharmacy Degree

5 Council on Pharmacy Management
   A. ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive
   B. ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems
   C. Health-System Use of Medications and Administration Devices Supplied Directly to Patients
   D. Human Immunodeficiency Virus (HIV) Positive Employees

11 Council on Pharmacy Practice
   A. ASHP Statement on Pharmacy Services to the Emergency Department
   B. ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System
   C. Standardization of Intravenous Drug Concentrations
   D. Disclosure of Excipients in Drug Products
   E. Biological Drugs

19 Council on Public Policy
   A. Education, Prevention, and Enforcement Concerning Workplace Violence
   B. Regulation of Dietary Supplements
   C. Appropriate Staffing Levels
   D. Medicare Prescription Drug Benefit
   E. Federal Review of Anticompetitive Practices by Drug Product Manufacturers
   F. Confidentiality of Patient Health Care Information

24 Council on Therapeutics
   A. ASHP Statement on Criteria for an Intermediate Category of Drug Products
   B. Pharmacist’s Leadership Role in Anticoagulation Therapy Management
   C. Generic Substitution of Narrow Therapeutic Index Drugs
   D. Dietary Supplements Containing Ephedrine Alkaloids
House of Delegates
Session—2008

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

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

Diane Ginsburg, Board Liaison

Council Members
Lea S. Eiland, Chair (Alabama)
Rafael Saenz, Vice-Chair (Pennsylvania)
Kathleen H. Bostinque (California)
Michael B. Cockerham (Louisiana)
Dianna L. Gatto (Washington)
Michael P. Gulseth (Minnesota)
Beverly A. Kroner (Colorado)
Teresa L. Pounds (Georgia)
Vickie L. Powell (New York)
Miriam M. Smith (Illinois)
Kathryn M. Clark, New Technician (Ohio)
Audrey J. Imberg, Student (Minnesota)
Douglas J. Scheckelhoff, Secretary

Policy Recommendations

A. Role of Pharmacy Interns
1 To foster changes in state practice acts and regulations that would define a scope of practice for pharmacy interns that is distinct from that of a pharmacy technician; further,

5 To explore and promote new staffing models that foster expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

Background
The Council discussed the decline in the number of students who work in pharmacy settings while in pharmacy school. Historically, pharmacy students were required to obtain experiential education in the form of internships (with requirements specific to each state, but usually 1500 hours) prior to being eligible to take the pharmacist licensure exam in their respective states. Nearly all state boards of pharmacy now permit students to obtain the internship or experiential hours required for licensure through their college-based experiential rotations; this often supplants the need for a student to serve a traditional internship. Many Council members believed the traditional internship work experiences served an important purpose that is not being addressed through current experiential rotations.

The Council saw great value in pharmacy students working as paid interns separate from their experiential rotations and believed their role should be broader in scope than that of a pharmacy technician. Although students working as technicians can learn a great deal about the medication system, numerous examples were cited in which pharmacy interns were given greater responsibility than that of a technician but less than that of a pharmacist. In these examples, the role was designed to help interns begin accepting responsibility for their work while learning how to apply their knowledge to the real-world aspects of health-system pharmacy.

In California, the board of pharmacy recently defined a scope of practice for pharmacy interns; this was cited as a good model for fostering such opportunities.

B. Standardized Pharmacy Technician Training as a Prerequisite for Certification
1 To advocate that completion of an ASHP-accredited pharmacy technician training program be a prerequisite for the Pharmacy Technician Certification Examination.

Background
The pharmacy profession’s lack of national training and education standards for pharmacy technicians has resulted in the development of a wide variety of training programs that vary in content, length, and quality. In addition to these programs, many technicians are trained on the job; they learn the necessary skills and procedures for their workplace but rarely gain deeper understanding of their work. Technicians may be able to perform a task efficiently but may not fully understand why they are doing it, why it is important, and what can happen if they do it incorrectly. As pharmacy practice advances, pharmacists will rely more heavily on well-qualified technicians to perform the distributive functions and manage pharmacy automation. It will become increasingly important for technicians to have solid education and training. It will be important for the pharmacy profession to support national standards for the education and training of pharmacy technicians in order to ensure that all technicians are prepared for their current and future roles.

ASHP standards for pharmacy technician training programs are the only recognized standards for such programs. The ASHP model curriculum, which provides guidance for programs seeking to meet the standards, has been endorsed by the American Association of

The Council found it ironic that the profession and state boards of pharmacy have begun to endorse certification of pharmacy technicians before endorsing national standards for training and education. Some individuals do not see the need for accredited standards for training and education; they think certification shows that an individual is qualified. But the ability to demonstrate the knowledge to pass a test does not necessarily mean that an individual possesses the necessary skills to perform the job functions or has the in-depth education to understand the significance of the work. It is unfortunate that support for the Pharmacy Technician Certification Examination (PTCE) has encouraged the development of online programs, some of them expensive, that do not meet any national standards but advertise that they will help individuals pass the PTCE.

Education and training usually precede an examination to demonstrate the knowledge and competence needed for practice. For example, the National Association of Boards of Pharmacy requires individuals to complete a program accredited by the Accreditation Council for Pharmacy Education (ACPE) before they can sit for the NAPLEX examination to become licensed to practice pharmacy. The Council believes that both should be an ASHP-accredited program before sitting for the PTCE.

The Council anticipated that PTCB might resist changing the current prerequisite for the PTCE (i.e., high school graduation) to a higher requirement. It is always difficult to change a credentialing process, because the marketplace becomes used to the status quo. However, PTCB should be encouraged to do what is right for the practice of pharmacy and the protection of the public. PTCB might wish to consider some of the same techniques for implementing change as were used by ACPE when it moved from two standards (B.S. and Pharm.D.) to one (Pharm.D. only) for pharmacy education. For example, ACPE announced an effective date well into the future, giving stakeholders ample time for making the change.

C. Collaboration Regarding Experiential Education

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

Background

Most schools of pharmacy have developed their student rotation schedules independently, on the basis of university, faculty, and student schedules. Since many hospital experiential sites now provide preceptors for students on rotation from more than one school, the various rotation schedules can be burdensome to hospitals and result in an inefficient model for teaching students. The Council discussed the potential value in having rotations scheduled year round so that students are participating in daily care for patients, rather than having students available intermittently as is now the case. With the growing number of schools and expanded pharmacy school enrollment, as many experiential sites as possible will be needed. Standardizing the length of rotations and coordinating the start and end dates could enable sites to accommodate more students; overlap periods could be eliminated and administrative tasks (such as orientation to the site) could be performed more efficiently.

Many Council members described their experiences with successful collaborative efforts. In many cases, efforts to partner and standardize have helped accommodate an increased volume of student rotations. Other benefits, such as pooling resources to support educational programs to develop preceptors, were noted. Council members cited many challenges with these collaborative efforts, however. A willingness to work together and negotiate traditional school-controlled schedules and the like is essential. Most members agreed that standardization at the national level would be very difficult and might add little benefit beyond what could be accomplished regionally.

The Council also noted that many schools do not have student rotations during summer months, holiday periods, or the month of December, whereas other schools place students in experiential rotations throughout the year. Although there would be benefit in having schedules aligned more closely with practice (i.e., year round), Council members expressed concern that teaching sites might begin to use students as staff if their rotations were expanded to align with hospital staffing schedules.

D. Entry-Level Doctor of Pharmacy Degree

1. To be an active participant in the Accreditation Council for Pharmacy Education (ACPE) process for the revision of accreditation standards for entry-level education in pharmacy; further,

5. To actively monitor the long-range impact that the single entry-level degree will have on residency education, availability of experiential training sites, graduate education, and continuing education programs, and the resulting health-system pharmacist applicant pool.

(Note: This policy would supersede ASHP policy 9809.)

Background

The Council discussed policy 9809, Position on the Entry-Level Doctor of Pharmacy Degree, as part of sunset review. Council members considered the wording to be dated. Much has occurred since the original policy was approved, and the policy needed substantive and editorial changes. Since the Doctor of Pharmacy degree is well established as the entry-level degree, Council members thought the first two paragraphs of the existing policy were unnecessary.

Policy 9809 reads:

To reaffirm the official policy of ASHP to support the Doctor of Pharmacy degree as the single entry-level degree for professional pharmacy practice; further,

To strongly encourage the development of viable and widely available external and nontraditional Doctor of Pharmacy degree programs; further,

To be an active participant in the American Council on Pharmaceutical Education (ACPE) process for the revision of accreditation standards for entry-level education in pharmacy; further,

To provide the ACPE with appropriate documents and background materials in order to demonstrate the ASHP position and support for ACPE’s intent on this important issue; further,

To actively monitor the long-range impact that the single entry-level degree will have on residency education, availability of experiential training sites, graduate education, and continuing education programs, and the resulting health-system pharmacist applicant pool.
Board Actions

Preceptors of Pharmacy Students. The Council recommended and the Board of Directors voted

To create tools and resources that can be used by preceptors of pharmacy students in developing learning objectives and competency goals for health-system pharmacy experiential rotations; further,

To facilitate efforts to develop the skills of preceptors in order to improve the quality of experiential education for pharmacy students through education, programs, tools, and other resources.

Much concern has been raised in recent years over whether new graduate pharmacists have the minimum competencies required for entry into hospital and health-system pharmacy practice. New pharmacy graduates often need considerable training and orientation before they can practice effectively in a hospital setting, and this need for remedial training seems to be increasing. The Council discussed the content of the pharmacy curriculum and whether it specifically addressed the needs of practice in hospitals and health systems. Council members discussed whether it would be desirable and feasible for ASHP to document the competency requirements for pharmacists entering practice in this sector of the profession and then to use such documentation to assess the adequacy of the standards for pharmacy education.

The current standards and guidelines of ACPE require student experiential rotations in institutional settings (for both introductory Pharmacy Practice Experiences and Advanced Pharmacy Practice Experiences) but are not specific on what competencies should be addressed. The Council members did not agree on the value of having the ACPE guidelines include more prescriptive competencies specific to health-system practice. The Council agreed that developing a list of health-system-related competencies that could serve as a guide to experiential preceptors would be helpful.

The Council noted that students now spend about 30% of their professional education time in experiential rotations. This significant expenditure of time warrants a commensurate effort by colleges to ensure that the needed competencies are mastered during these experiences. Council members expressed concern that some schools are more effective than others in this regard.

Demonstrating the Value of Standardized Pharmacy Technician Training. The Council recommended and the Board of Directors voted

To foster research that seeks to demonstrate and document the value of standardized pharmacy technician education, training, and certification.

The Council discussed the importance of pharmacy technicians completing an ASHP-accredited technician training program, becoming PTCB certified, and becoming registered by state boards of pharmacy, consistent with ASHP policy 0412. Council members thought that having evidence of the impact of technician education, training, and certification on quality, safety, and efficiency would be beneficial and would help in gaining the support of state boards of pharmacy. Data on the cost-to-benefit equation for technician training would help gain the support of employers. It was noted that not all pharmacy practice settings place a high value on pharmacy technician training or certification. Pharmacy groups in some states have directly opposed proposals for regulatory requirements for technician training. Having documented evidence would help develop the needed support.

Requirement for Pharmacy Student Rotations in Rural or Underserved Areas. The Council recommended and the Board voted

To explore the implications of requiring that one or more pharmacy student rotations be carried out in a setting serving a rural or other medically underserved population.

The Council discussed whether there would be value in advocating a requirement of at least one student rotation in a rural or otherwise underserved area. The Council on Public Policy discussed a related agenda item. There continues to be a health care workforce shortage in rural hospitals and clinics caring for underserved populations. Many colleges are located in urban areas with limited access to rural settings, so the inclusion of underserved areas would make this a practical recommendation as well as improving access for this group of patients.

The Council discussed whether the skills learned in urban and underserved areas are any different from those learned in mainstream locations. The conclusion was that the skills are not different, but that there is great value in learning about the culture and challenges encountered in these settings. Many times, a student’s exposure to a new practice area stimulates interest that leads to career choices that might otherwise not have been considered. Council members noted that a requirement for such rotations would reinforce ASHP’s position on professionalism and diversity. Council members believed that this issue should be researched and brought back for further discussion at the next meeting.

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.)

- Patient-Centered Care (0313)
- Cultural Competence (0314)
- Practice Sites for Colleges of Pharmacy (0315)

Other Council Activity

Preferred Experiential Rotations for Students Planning to Seek Residency Training. The Council discussed whether there was value in identifying specific rotations for students who plan to seek a residency after graduation. The Council discussed how such rotations would be identified and who might receive preferential access. Some members described programs they have established informally that entail several years of mentoring before entry into a residency. In these cases, there are rotations for which the students being mentored receive preferential selection. Concerns were raised over the idea of reserving rotations, since all students pay the same tuition and deserve equal access to educational opportunities. Many students come to their faculty and preceptors for direction and advice. Since the advice depends on the individual student’s career objectives and other experiences and the rotations available, the Council did not make specific recommendations.

Graduates of Foreign Schools of Pharmacy. The worldwide shortage of pharmacists is resulting in many changes in pharmacy education. The rapid expansion of the number of pharmacy schools and the overall enrollment is one such response. Similar to what has happened in nursing, foreign schools of pharmacy may spring up that are designed to produce pharmacists who can become licensed
in the United States. The Council reviewed ASHP policy 0323 calling for pharmacy schools to be ACPE accredited (whether domestic or foreign) and found it to be sound.

Council members discussed the current requirements of completing the Foreign Pharmacy Graduate Equivalency Exam (FPGEE) and Test of English as a Foreign Language (TOEFL), verification of credentials, and successful completion of the NABPEX examination and the Multistate Pharmacy Jurisprudence Examination (MPJE). The process and requirements now in place were considered to be adequate for fully evaluating the competency of foreign graduates. No specific recommendations were made by the Council.

Pharmacist Practitioner. Nurse practitioners and physician assistants are commonly seen in physician offices, emergency departments, clinics, and other settings. They are recognized as providers and are able to bill for their services. These provider positions were established as physician-extender roles and are likely to be in higher demand with the anticipated physician shortage.

The Council discussed whether a “pharmacist practitioner” designation would require a separate licensure category or some other recognized set of credentials. Council members discussed the adoption of a legally recognized model in New Mexico in which the core credential for being a pharmacist practitioner is the completion of a residency. This seems to have simplified the process of defining who is qualified to be reimbursed for clinical services. Many Council members regarded the designation as just a title with no real credentials to support it. Furthermore, it was not clear what organization or credentialing body might appropriately confer the designation.

It was the consensus of the Council that privileging and credentialing do and should occur at the local level. Council members concluded that a preestablished designation such as pharmacist practitioner, with its own set of credentials, was not desirable at this time.

Preceptor Training and Development. The Council discussed the need to develop pharmacy preceptors. ASHP’s book for preceptors and plans for its revision were discussed. Several Council members voiced a need for a preceptor development tool on a smaller scale than an entire book, in a video format lasting two or three hours, for use in a variety of settings. This might be particularly helpful to schools, since ACPE accreditation guidelines will soon require schools to document preceptor training at all sites.

White Paper on Pharmacy Technicians 2002: Needed Changes Can No Longer Wait. The Council reviewed the white paper on pharmacy technicians endorsed by ASHP and other organizations. The document was considered to be timely and was thought to support well ASHP policies related to pharmacy technicians. However, the Council voiced some frustration over a perceived lack of progress in realizing many of the changes called for in the document. No specific changes were identified.
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.

Stanley S. Kent, Board Liaison

Council Members
Wayne S. Boheneck, Chair (Ohio)
David J. Blanchard, Vice-Chair (New York)
Eugene A. Handza (Kansas)
Phillip E. Johnson (Florida)
Vivian B. Johnson (Texas)
Paul S. Knecht (Louisiana)
Dawn Moore-Jefferson (Indiana)
Joe E. Ness (Washington)
Ashok B. Ramalingam (Virginia)
Jennifer Tryon (Oregon)
Thomas E. Kirschling, New Practitioner (Pennsylvania)
Jeffrey D. Little, Student (Kansas)
Edward C. Stemley, Secretary

Policy Recommendations

A. ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive
1. To approve the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive (Appendix A).

Background
The Council and the Board believed that ASHP needs to make a statement about the importance of pharmacy leadership having a reporting relationship not more than one layer removed from the organization’s principal executive officer (e.g., the chief executive officer). The Council and the Board agreed that this statement will be helpful in educating health-system executives about the potential benefits of such a reporting structure, such as improved timeliness and accuracy of information from pharmacy about issues affecting medication use.

B. ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems
1. To approve the ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems (Appendix B).

Background
The Council and the Board believed that a high-level, principles-oriented, philosophical statement about the standards-based characteristic of health-system pharmacy practice will help pharmacy practitioners in health systems articulate their commitment to high standards of care, including ASHP best practices, and inspire pharmacists to identify gaps in their own practices and work to close those gaps.

C. Health-System Use of Medications and Administration Devices Supplied Directly to Patients
1. To encourage hospitals and health systems not to permit administration of medications brought to the hospital or clinic by the patient or caregiver when storage conditions or the source cannot be verified; further,
2. To support only care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,
3. To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients) unless it is determined that the risk of not using such a device exceeds the risk of using it; further
4. To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices.

(Note: This policy would supersede ASHP Policy 0706.)

Background
The Council believed it would be useful to expand existing policy
0706, Administering Injectable Medications Directly to Patients, which reads:

To encourage hospitals and health systems not to permit administration of injectable medications brought to the hospital or clinic by the patient or caregiver when storage conditions or the source cannot be verified; further,

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

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

The Council discussed the implications of using patients’ own infusion devices. Council members believed there are serious patient safety and liability issues for staff when the use of such devices is allowed. Devices unfamiliar to staff are particularly risky. There are, however, occasions when the benefits of using patients’ own devices may outweigh the risks.

The Council believed the policy should be expanded to deal with all medications, not just injectable ones. In addition to the proposed policy revision, the Council encouraged the development of guidance about criteria for ensuring safe and appropriate administration of medications and use of administration devices brought into facilities by patients.

D. Human Immunodeficiency Virus (HIV) Positive Employees

1. To discontinue policy 9201, Human Immunodeficiency Virus (HIV) Positive Employees, which reads:

3. To adopt the position that mandatory routine testing of health care workers for infection with the human immunodeficiency virus is unnecessary; further,

6. To support the use of universal precautions for infection control.

Background

The Council discussed policy 9201 as part of sunset review. Noting that mandatory routine testing is not conducted now, the Council believed this policy is no longer needed. Further, given current privacy mandates, it is unlikely that managers would know about employees’ HIV-positive status. The Council believed, however, that there might be merit in developing future policies or guidance about communicable diseases.

Board Actions

Practice Model for Inpatient Hospital Pharmacy. The Council recommended and the Board of Directors voted

To convene a multidisciplinary summit to conceptualize the characteristics of an optimal inpatient hospital pharmacy practice model.

The Council acknowledged that it had been some time since the fundamental practice model for inpatient hospital pharmacy services had been reexamined. ASHP and hospital pharmacists were instrumental in conceptualizing, researching, and actualizing a practice model change in the 1960s (and thereafter) in the form of the unit dose drug distribution and control system. Although there were some interdisciplinary features built into the model, it was primarily a product-distribution (and related safety) improvement. The next major practice model change was the emergence of clinical services and direct patient care by pharmacists, which began in the 1970s and is becoming more common today. ASHP has been a leading force in promoting those roles, driven by members’ belief that these are the roles to which hospital and health-system pharmacists need to evolve. In general, however, pharmacists still devote most of their time to services and activities other than directly managing the therapy of individual patients, and the proportions of time spent on distributive and clinical services are fairly stable.

Conceptualizing a new practice model built on an integrated, interdisciplinary care team might serve patients and hospital pharmacy well. Furthermore, this may be an opportune moment for such change, given the ASHP Vision Statement for Pharmacy Practice in Hospitals and Health Systems, the ASHP Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems, and the Joint Commission of Pharmacy Practitioners recent Future Vision of Pharmacy Practice. The Council believed there is a need for new and vigorous thinking about an inpatient pharmacy practice model that will move hospital and health-system pharmacy along more assertively toward the goal of most pharmacists’ spending most of their time in direct patient care (managing the therapy of individual patients).

ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems. The Council recommended and the Board of Directors voted

To approve the ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems.

The guidelines describe techniques for managing medication costs in inpatient settings and hospital clinics. They offer methods for cost management through purchasing and inventory management, including

- Using group purchasing organization, facility, and wholesaler contracts to reduce purchase costs;
- Maximizing use of generic medications;
- Reducing wholesaler and distribution fees; and
- Optimizing inventory management through wholesaler ordering programs, facility storage strategies, and waste reduction.

The guidelines also provide advice on planning, developing, and implementing medication utilization management programs to reduce costs, including recommendations for

- Assessing medication costs,
- Analyzing data for medication utilization programs,
- Building medical staff support,
- Enhancing the role of clinical pharmacy services in cost management, and
- Implementing formulary management techniques (therapeutic interchange, guidelines and protocols, and pharmacist interventions such as dosage form changes, renal dose adjustments, medication restrictions, and repackaging).

The guidelines will be published in an upcoming edition of the American Journal of Health-System Pharmacy and are available on the ASHP website at www.ashp.org/g_ashp/cat2cn.asp?CID=510&DID=552. The new guidelines supersede the ASHP Technical Assistance Bulletin on Assessing Cost-Containment Strategies for Pharmacies in Organized Health-Care Settings,
which is available at www.ashp.org/s_ashp/docs/files/BP07/Mgmt_TAB_Strategies.pdf.

Sunset Review of Professional Policies and Guidance Documents. As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and were found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Pharmacy Drug Theft (0303)
- Machine-Readable Coding and Related Technology (0308)
- Unit Dose Packaging Availability (0309)
- Technician-Checking-Technician Programs (0310)
- Multidisciplinary Action. Plans for Patient Care (9304)
- Medication Misadventures (9805)
- ASHP Guidelines on Outsourcing Pharmaceutical Services

Other Council Activity

Inpatient Drug Distribution in Hospitals. The Council voted

To develop guidance about the desired principles and characteristics of inpatient drug distribution in hospitals and about emerging technology that may influence distribution.

Numerous configurations exist for inpatient drug distribution in hospitals (e.g., manual distribution through satellite pharmacies, manual centralized distribution via unit dose carts and pneumatic tubes, automated cabinets in patient care units, and centralized robotics). Hybrid configurations are common. Most configurations are imperfect in that medications are not controlled by pharmacists from beginning to end. The Council believed it would be useful to develop guidance that practitioners could use to evaluate drug distribution configurations. The guidance could be in the form of formal guidelines, Web resource material, and publications and could be featured in educational programs.

It is important for ASHP to do this because many distribution products and services are available, and, without guidance, practicing pharmacists (or others making decisions about these products and services) could overlook important principles and characteristics in their selection and implementation.

ASHP Guidelines on Recruitment, Selection, and Retention of Pharmacy Personnel. The Council voted

To revise the ASHP Guidelines on Recruitment, Selection, and Retention of Pharmacy Personnel.

The Council discussed this practice standard as part of sunset review. The document was considered to be still relevant and important. However, the Council believed several topics should be added, including behavioral interviewing, peer interviewing, the checking of references, the use of recruitment firms, and the use of temporary staff. Possibly, the document should also provide direction for the interviewee. The literature references should be updated. The current document should be retained as active while revision proceeds.

Hospital Pharmacy Department of the Future. As a part of its public policy initiatives, the Joint Commission convened a roundtable of invited experts in January 2006 to evaluate the current health care environment and identify elements that hospitals of the future will need in order to meet the needs of patients. In April 2007, the Joint Commission hosted a capstone symposium on the hospital of the future. ASHP was a participant in these activities. The nursing profession, spotlighted in the Joint Commission's work, presented some compelling research about workflow and staffing. In any further planning for hospitals of the future, hospital and health-system pharmacists need to be strong advocates for consideration of the changing practice models of various professions and advances in medication technology (more time spent by pharmacists in direct patient care, new pharmaceutical delivery systems, pharmacogenomics, biologics, gene therapy, personalized medicine, and so on). The physical design of pharmacy spaces for the future must accommodate those changes, and ASHP should work to educate leading architects about the coming changes.

Magnet Status for Medication Use in Hospitals and Health Systems. 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.

Opportunities to Promote ASHP Resources. The Council compared the services and information offered by ASHP with those of other groups offering value-added services. The Council believed that ASHP has sufficient policies to meet members' needs but that it could use more assertive methods of communicating with members about its policies and other resources. Promotional efforts should include educational programs and tools to guide members in appropriate use of ASHP resources.

The Council believed that ASHP is not taking advantage of one of its greatest attributes: the ability to share information among members. It would be helpful to have better archiving, searching, and retrieval mechanisms for obtaining the valuable resources ASHP offers. Information on specific topics could be compiled from electronic discussion groups and made available to members in a searchable format. Types of information that would be valuable to share include policies and procedures, job descriptions, and technology assessment tools.

ASHP is an important source of continuing education. Numerous groups (e.g., wholesalers) dispatch representatives to meet regularly with pharmacy department staff. ASHP should consider collaborating with some of those groups to convey the availability of ASHP products and services, including continuing education. In addition, practitioners often look for available continuing education near the end of their license renewal cycles; ASHP should view this as an opportune time for marketing continuing education.

Documenting the Cost and Benefits of Mandated Infrastructure Changes. Hospitals and health systems adhere to externally developed standards as a means of ensuring high-quality services. Implementing such external standards can create budgeting challenges for pharmacy departments. Pharmacy managers are called upon to explain the increased costs in terms of the costs and benefits that will ensue from making the changes.

The Council believed pharmacy managers need assistance in documenting those costs and benefits. ASHP should consider developing tools for documenting the benefits and the human, material, and capital costs of successfully implementing and managing mandated operational changes. In addition, ASHP should provide good data to regulatory agencies with respect to the financial implications of compliance.
Appendix A—ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

Position

The American Society of Health System Pharmacists (ASHP) believes that complex hospitals and health systems benefit from having a pharmacy executive responsible for the design, operation, and improvement of the organization’s medication-use process. This individual (sometimes referred to as the “chief pharmacy officer,” but hereinafter “the pharmacy executive”) must be properly positioned within the organization to ensure the best utilization of his or her expertise in all decisions regarding medication use. To promote effective communication, collaboration, and teamwork with peers, the pharmacy executive should

- Be involved in the organization’s strategic planning regarding all components of the medication-use process;
- Report directly to the organization’s principal executive (e.g., the chief executive officer [CEO] or chief operating officer [COO]);
- Have a title internally consistent with others reporting at that organizational level;
- Participate in regularly scheduled CEO- or COO-level meetings; and
- Be a member of the medical executive committee (or its equivalent).

Background

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

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

Qualifications and Responsibilities of the Pharmacy Executive

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

What distinguishes the pharmacy executive from the established director of pharmacy position is a deeper knowledge of the organization’s operations and a greater degree of involvement in the organization’s strategic planning and decision-making processes. The pharmacy executive provides the organization with pharmacy’s unique clinical and business perspective on discussions and decisions related to changes in medical and surgical practice and to operational changes. He or she has experience leading evidence-based decision-making about drug use, controlling pharmaceutical expenses while maximizing patient benefit through the formulary system. The pharmacy executive has in-depth knowledge of the pharmaceutical supply chain, clinical therapeutics, physician prescribing habits, the medication-use process, medication-use policy, and the technology used to deliver and support patient care, and about how those issues affect the overall success of the organization. The pharmacy executive understands the relationships between third-party requirements, coding, documentation, billing equations, pricing updates, and organizational resources, and can provide quality assurance for all these functions, improving financial performance. The pharmacy executive’s responsibilities include but are not limited to the following strategic planning, designing, implementing, and improving the medication-use system; ensuring quality outcomes through performance improvement activities; leading drug utilization efforts; optimizing use of information systems and technology; managing the pharmaceutical supply chain, pharmacy department financial operations, and human resources; ensuring compliance with regulatory and accreditation requirements; fulfilling the organization’s research and educational missions; and providing institutional representation and leadership. The pharmacy executive fulfills these responsibilities through his or her own actions, through proper delegation to competent individuals on his or her staff, and through collaborative efforts with other health care professionals.

Strategic Planning. The pharmacy executive assesses the health care environment, identifying opportunities to improve medication use and medication-use systems. In the organization’s strategic planning, he or she provides pharmacy’s perspective on how changes in the use of pharmaceuticals and related technology may impact systems in the future.

Medication-use System Management. The pharmacy executive is responsible for overseeing the design, implementation, and management of a safe and effective medication-use system. He or she ensures that systems are developed and improved based on evidence and best practices, operate effectively and efficiently across the continuum of care, and are continuously evaluated and improved using contemporary quality improvement methods. The pharmacy executive is responsible for developing plans for the continued operation of medication-use systems and for the provision of pharmaceutical services during emergencies and disasters.

Quality Outcomes and Performance Improvement. The pharmacy executive ensures that the medication-use system is continuously evaluated and improved using contemporary quality improvement methods. The pharmacy executive provides leadership at the organizational level to ensure that pharmacists are positioned to improve the quality and safety of medication use throughout the health system. The pharmacy executive (or his or her designee) should be a member of all the institution’s key committees responsible for performance improvement activities related to medication use and patient safety. The pharmacy executive and his or her staff must be intimately involved in the development and implementation of medication use. The pharmacy executive should give particular attention to patients in high-risk areas (as identified by organizations such as the Centers for Medicare and Medicaid Services and the Joint Commission) to ensure that pharmacy services meet patient care needs and that drug therapy is as safe, effective, and economical as possible. The pharmacy executive (or a designee) is a member and active participant of the infection control committee and ensures that infection control principles are applied to the prescribing, dispensing, and administration of antimicrobials.

Drug Utilization Management. The pharmacy executive collaborates with peers to develop drug utilization and formulary initiatives that optimize therapeutic outcomes, reduce the risk of drug-related problems, and ensure the use of cost-effective pharmacy therapy throughout the health system. The pharmacy executive minimizes inappropriate utilization and leads efforts to modify practices to improve medication use.

Informatics and Technology. The pharmacy executive leverages technology and automated systems to optimize the medication-use system. He or she has responsibility for ensuring that information systems and technology used in the pharmacy and patient care environments maximize the safety, effectiveness, and efficiency of medication prescribing, dispensing, and administration. The pharmacy executive provides leadership at the organizational level....
regarding planning, purchasing, implementing, and maintaining health records, computerized prescriber order entry systems, smart pumps).

Supply chain management. The pharmacy executive is responsible for all pharmaceutical contracting, procurement, receiving, security, inventory control, diversion prevention, and distribution policies, including reverse distribution and other methods of pharmaceutical waste disposal. He or she ensures that the methods used to contract and obtain products are safe, cost effective, and timely. The pharmacy executive is also responsible for emergency preparedness of the supply chain.

Financial management. The pharmacy executive manages the health-system pharmacy’s financial performance within the context of the broader health system. He or she develops budgets aligned with organizational and departmental objectives and monitors financial performance appropriately, performing financial audits and analysis as needed to ensure accurate, appropriate, and timely recording and classification of actual revenue capture and expenses.

Human resources management. The pharmacy executive manages the health-system pharmacy’s human resource efforts. These efforts include determining the appropriate numbers and types of staff required to meet patient care needs, satisfy regulatory and accrediting requirements, and achieve the institution’s mission. The pharmacy executive ensures effective and timely staff recruitment, orientation, training, education, mentoring, career development, performance review, and retention efforts.

Regulatory and accreditation compliance. The pharmacy executive ensures continued compliance with all national, state, and local regulations related to medications and their use. He or she is responsible for implementation of Joint Commission medication management standards and National Patient Safety Goals related to medications, for maintaining ASHP accreditation where applicable (e.g., residency and technician training), and for implementation of best practices.

Research and educational missions. The pharmacy executive has an integral role in supporting the organization’s research and educational missions by overseeing investigational drug services, fostering staff and resident research, and managing student and residency educational programs.

Institutional representation and leadership. The pharmacy executive demonstrates the personal leadership qualities and business acumen essential to operate effectively within the health system and to advance the profession and practice of pharmacy. He or she serves as the primary pharmacy representative on relevant committees of the organization’s leaders to ensure that medication-use systems and pharmaceutica services meet the needs of patients and health care providers across the continuum of care. The pharmacy executive assumes a leadership role within the profession through active participation in local, state, and national professional associations.

Conclusion
Complex hospitals and health systems should have a pharmacy executive responsible for the design, operation, and improvement of the organization’s medication-use process. This individual must be properly positioned within the organization to ensure the best utilization of his or her expertise in all decisions regarding medication use.

References

John E. Clark, Pharm.D., Fuss J. Lazzaro, M.S., and Douglas A. Miller, Pharm.D., are gratefully acknowledged for drafting this statement.

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Appendix B—ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems

Position
Pharmacy practice leaders in hospitals and health systems have a distinguished history of advancing health-system pharmacy practice beyond the minimum required by law, regulation, and accreditation. The American Society of Health-System Pharmacists (ASHP) supports those efforts by developing and disseminating a comprehensive body of evidence-based, peer-reviewed descriptions of best practices in health-system pharmacy. ASHP believes that pharmacists who practice in hospitals and health systems (“health-system pharmacists”) and pharmacy leaders in health systems can continuously improve the delivery of patient care by regularly assessing compliance with ASHP best practices, identifying gaps in practice, establishing practice improvement priorities appropriate for their unique circumstances, and working to close the targeted gaps.

Purpose
The purpose of this statement is to promote understanding of how health-system pharmacists use ASHP best practices to develop and promote in health systems a standard of practice that exceeds what is required by law, regulation, or accreditation.

Standards-based Pharmacy Practice
A practice standard is “a statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality care, treatment, and services.” In health care, practice standards serve as guidelines for a profession and as a way of communicating to peers, patients, policy-makers, other professionals, and the public the roles and responsibilities of members of the profession. Practice standards also provide a benchmark for evaluating the quality of services and patient care. Health-system pharmacists, like other health care professionals, practice under a number of mandated standards. These standards include state board of pharmacy regulations, public health requirements, Drug Enforcement Administration regulations, Joint Commission accreditation standards, Centers for Medicare and Medicaid Services (CMS) Conditions of Participation, and the standards of other accrediting bodies and professional associations. Individual health care organizations also develop their own interdisciplinary practice policies and standards of care related to medication use, with health-system pharmacists as key participants in their development.

ASHP members have invested decades of effort in developing and maintaining an extensive body of policy positions, statements, and guidelines (hereinafter “ASHP best practices”) that serve as a guide for effective, high-quality pharmacy practice in hospitals and health systems. This comprehensive set of policies is unique in pharmacy.

ASHP best practices reinforce health-system pharmacists’ established roles in health care and encourage development of responsibilities that answer the growing need and public demand for expanded involvement of pharmacists in patient care. They are based on professional and scientific literature and are developed with input from ASHP members, the public, regulatory bodies, other professional associations, and representatives of other health care disciplines. Peer groups of ASHP expert members systematically review and evaluate ASHP best practices against existing literature, the changing expectations of society, and changes in the professional and ethical challenges faced by health-system pharmacists.

A compilation of these documents is published annually as Best Practices for Hospital & Health-System Pharmacy and made available to the public (www.ashp.org/bestpractices).

Most ASHP best practices represent the professional beliefs and aspirations of pharmacists practicing in health systems, based on evidence and expert opinion. Only three ASHP guidelines describe a minimum level of practice that all hospital pharmacy departments should consistently provide; these guidelines are designated as ASHP minimum standards.

ASHP best practices have been used as guidance by regulatory and accrediting bodies such as CMS, state boards of pharmacy, and the Joint Commission, as well as by courts of law. Institutions that offer ASHP-accredited residencies are required to meet ASHP best practices to ensure the quality of the educational experience.

ASHP best practices represent a commitment by ASHP members to advancing the standard of practice pharmacy. ASHP believes that all health-system pharmacists have a role to play in raising health-system pharmacy practice to a level consistent with the best practices that have been developed and have gained acceptance by peer-reviewed, consensus-based process. Practicing pharmacists and pharmacy leaders in health systems should use their professional judgment to regularly assess compliance with ASHP best practices, identify gaps in practice in their settings, establish practice improvement priorities appropriate for their unique circumstances, and work to close those practice gaps to ensure continuous improvement in the delivery of patient care.

Conclusion
Health-system pharmacy practice leaders have a long tradition of striving to advance practice beyond the minimum required by law, regulation, and accreditation. ASHP best practices embody those aspirations and provide health-system pharmacists with a means to continuously improve the delivery of patient care.

References

Scott Mark, Pharm.D., M.S., M.Ed., CHE, FASHP, FABC is gratefully acknowledged for drafting this statement.

Approved by the ASHP Board of Directors on March 7, 2008. Approval by the ASHP House of Delegates is pending. Developed through the ASHP Council on Pharmacy Management.

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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.

James G. Stevenson, Board Liaison

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Deborah R. Saine (Virginia)
Jamie S. Sinclair (Minnesota)
Kasey K. Thompson, Secretary

A. ASHP Statement on Pharmacy Services to the Emergency Department
1. To approve the ASHP Statement on Pharmacy Services to the Emergency Department (Appendix A).

Background
The Council and Board of Directors believed that this Statement will serve as a strong foundation to help hospitals, health systems, accrediting bodies, and others focus efforts on ensuring the safety and quality of the medication-use process in emergency departments (EDs). The Council and Board acknowledged that not all hospitals and health systems can support having pharmacist staffing in the ED. However, both groups believed that the safety and quality of the medication-use process in the ED should be equivalent to that of the rest of the organization and, therefore, that pharmacy departments should take a leadership role in ensuring that patients are safe and medication therapy is optimized, regardless of whether pharmacists are physically present in the ED.

B. ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System
1. To approve the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System (Appendix B).
2. (Note: This Statement would supersede the ASHP Statement on Pharmacy and Therapeutics Committee dated November 20, 1991, and the ASHP Statement on the Formulary System dated November 18, 1982.)

Background
The Council and Board of Directors believed that this revised Statement will continue to serve as the basis on which hospitals and health systems structure pharmacy and therapeutics (P&T) committee activities and develop sound formularies based on patient safety. In addition to this revised Statement, the ASHP Guidelines on Formulary System Management has been updated and is available on the ASHP website.

C. Standardization of Intravenous Drug Concentrations
1. To develop nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given as continuous infusions; further,
2. To encourage all hospitals to use infusion devices that interface with hospital information systems and include standardized drug libraries with dosing limits,
3. clinical advisories, and other patient-safety-enhancing capabilities.

Background
The Council reviewed numerous articles and case studies describing patient harm that resulted from a lack of standardization of intravenous drug products by manufacturers and from inconsistent practices by health care professionals and organizations. The Council believed and the Board of Directors agreed that it would be possible to develop a list of nationally standardized concentrations of high-risk intravenous drugs that, with few exceptions, should be used throughout the entire health care system. The Council also suggested that dosing units for these drugs should be
standardized. An example of dosing unit standardization would be selecting either micrograms per kilogram per minute or micrograms per minute, as opposed to using both.

The Council recognized that the culture of health care would make implementation of a national standard difficult, but it encouraged ASHP to take a leadership role in working with other key stakeholders to move practice and industry in the direction of standardization. The Council also considered the need for hospitals to minimize the number of concentrations of any given drug and noted the value of having all high risk drugs available in premixed form. It was further noted that technology vendors need to work with practitioners to determine the appropriate field length in various computerized systems so that new and dangerous abbreviations are not continually being invented.

The Council believed and Board agreed that infusion devices that interface with hospital information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities have proven to be safer than the pumps of the past, and that a goal should be established for having all hospitals implement this technology. The Council understood the financial implications of such a recommendation but believed strongly that implementing the use of this technology is the right thing to do to prevent harm to patients.

**D. Disclosure of Excipients in Drug Products**

1. To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label.

(Note: Derivative source means the botanical, animal, or other source from which the excipient is originally derived.)

**Background**

The Council believed and the Board of Directors agreed that health care professionals should have access to the name and derivative source (botanical and nonbotanical) of all excipients used in drug products, and that this information should be included on the official label (which includes the package insert) for the drug product. The rationale for this policy is that in some cases chemically inert excipients can serve as potential allergens and autoimmune response inducers (such as the effect of gluten in patients with celiac disease), and that having ready access on the official label to the name and derivative source of the excipients used in drug products would support health professionals and patients in the prevention and identification of certain allergies. When applicable, information about major allergy-inducing contaminants should also be included in the official label. Examples of major food allergens are listed in the Food Allergen Labeling and Consumer Protection Act of 2004. These allergens include milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. Although many of these food allergens are not commonly used in pharmaceutical excipients, some are used frequently, including wheat starch and corn starch (diluent, disintegrant), peanut oil and soybean oil (vehicles), and lactose (a milk derivative used as a diluent).

The Food Allergy & Anaphylaxis Network has embarked on an initiative to identify and compile a list of allergy-inducing excipients used in prescription and nonprescription drug products. Additional work in this area is being done by the United States Pharmacopeia. ASHP staff are currently involved in both initiatives.

**E. Biological Drugs**

1. To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of biologic therapies, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

6. To facilitate education of pharmacists about the proper use of biologic therapies.

(Nota: Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) defines biological product as follows: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allenergetic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.)

(Note: This policy would supersede ASHP policy 0316.)

**Background**

The Council and the Board believed that this policy should be revised to include the official food and Drug Administration (FDA) definition of “biological product” as a note. Policy 0316 reads as follows:

To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of biologic therapies, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

To facilitate education of pharmacists about the proper use of biologic therapies.

**Board Actions**

**Celiac Disease.** The Council recommended and the Board voted

To educate health-system pharmacists about celiac disease and the exacerbating effects of gluten found in certain foods and drug product excipients; further,

To foster definitive research on the influence of gluten in drug products on celiac disease.

The Council reviewed numerous articles on celiac disease and how the cumulative effect of gluten from multiple sources (including drug products) can exacerbate the disease. It is still undetermined whether a drug product that contains a certain number of parts per million of gluten could exacerbate celiac disease. However, it is suspected that gluten from multiple sources when combined over a short period of time can exacerbate the disease. Given the prevalence of celiac disease in the United States (estimated at 1%) and the morbidity the disease can cause, the Council believed that this issue was a concern for health-system pharmacists. The Council and Board of Directors believed that more research needs to be conducted to definitively determine the relative influence of gluten in drug products on celiac disease. The Council and Board also noted that health-system pharmacists need to be knowledgeable about celiac
disease and the exacerbating effects of gluten found in certain foods and drug product excipients.

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.)

Other Council Activity

**ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents.** The Council voted

To revise the ASHP Guidelines on Preventing Medication Errors with Antineoplastic Agents.

The Council believed that contemporary issues and new literature need to be addressed in this document. Intrathecal vincristine errors were noted as a common source of serious harm that should be addressed. The Council believed a definition of “antineoplastic drug” should be included in the guideline. It was noted that the use of oral chemotherapeutic agents is increasing and that best practices associated with the safe use of these agents should be addressed in more detail. Council members also commented that most computerized prescriber order entry systems do not support oncology drugs, which is another issue that should be addressed in the revised document.

**ASHP Statement on the Pharmacist's Role in Infection Control.** The Council voted

To revise the ASHP Statement on the Pharmacist’s Role in Infection Control.

Each year, approximately 2 million people in the United States contract a hospital-acquired infection. An increasing number of hospital-acquired infections are attributed to organisms that are resistant to antimicrobials. Further, studies suggest that as much as half of all antimicrobial use is inappropriate. Recommendations for preventing and reducing antimicrobial resistance in hospitals stress the importance of improving antimicrobial use at the institutional level; this is referred to as antimicrobial stewardship.

The Council reviewed this Statement in the context of a discussion on the pharmacist’s role in antimicrobial stewardship. The Council suggested that the current Statement be expanded to a guideline, and that it should be made more widely applicable to settings other than just large hospitals (e.g., small and rural hospitals). The current Statement addresses stewardship and infection control in broad terms that may not be applicable or feasible in smaller institutions.

**Accountability.** The Council discussed accountability (and shared accountability) in the context of pharmacy practice in hospitals and health systems. The Council noted that a core element of pharmaceutical care is that pharmacists share in the responsibility for patient outcomes. However, the Council questioned whether pharmacists have taken this responsibility seriously by taking full ownership of and accountability for the entire medication-use process.

Council members noted that the perception of the public, other health professionals, and hospital leadership is that pharmacists are responsible and held accountable only for the acquisition, storage, and dispensing of medications (i.e., product-related elements of medication management), and not for patient outcomes from medication use. The Council strongly believed that this mindset needs to change, first among hospital and health-system pharmacists.

**Gene Therapy.** The Council discussed facilities requirements for pharmacy departments that are preparing gene therapies, the roles and responsibilities of pharmacists in patient education on these therapies, and whether gene therapy will likely become a mainstay of therapy and, if so, whether it likely will be available only in highly specialized centers. Council members believed existing ASHP policy provides sufficient basis for the Society to engage in enhanced initiatives (policy or programmatic) to prepare pharmacists for future roles in gene therapy.

The Council believed there are similarities between the evolution of nuclear pharmacy and gene therapy that ASHP needs to consider. The Council expressed the hope that gene therapy will not diverge from traditional pharmacy practice to the extent that nuclear pharmacy has at the regulatory, credentialing, and practice levels.

**Rethinking Current Approaches to Medication-Use System Safety.** Despite widespread awareness of common medication-safety-related problems and, to various degrees, implementation of quality improvement techniques, there continue to be frequent and harmful errors due to well-known problems such as the use of abbreviations, intrathecal administration of vincristine, and errors involving anticoagulants, insulin, and opiates.

The Council discussed whether an entirely new hospital-level model and systems-based approach to preventing harm associated with medication use are needed, and what role ASHP might play in fostering the development of a new framework for medication-use safety and quality in hospitals and health systems. The Council believed that the system is in need of fundamental change but understood that such change would take considerable time, effort, and resources because of the overarching culture in health care, as well as very real health care financing issues.

**Improving Medication-Use Quality through Pay for Performance.** The Council discussed the roles pharmacists should play to help organizations achieve high levels of compliance with evidence-based performance indicators associated with medication use, including the indicators currently required for public reporting by the Centers for Medicare and Medicaid Services, states, and private health plans.

Council members noted that many pharmacy departments are not as engaged as they should be because other departments such as performance improvement or quality, which are often led by nurses, “own” the issue, including the medication management components. The Council encouraged ASHP to continue using the ASHP Quality Improvement Initiative to enhance members’ knowledge and understanding of the pay-for-performance concept and how it relates to pharmacy practice. The Council agreed that pharmacy should be a major stakeholder in all efforts in hospitals that are related to medication-use quality, which include the use of performance indicators and pay-for-performance incentives.

**Health Literacy.** The Council believed that this is a very important patient safety topic on which ASHP should focus attention in multiple areas. The Council was pleased to learn that the International Pharmaceutical Federation (FIP) and the World Health Organization (WHO) have identified health literacy as a top priority. The Council strongly encouraged ASHP to align its efforts with those of FIP and WHO and also to seek opportunities to infuse health literacy into the research agenda of the ASHP Research and Education Foundation and the ASHP 2015 initiative.
Pharmacist's Role in Surgical Settings. The Council recognized that there is a perception among most hospital leaders and other health professionals that pharmacists have a limited role in the broader medication-use process in the operative and perioperative settings. Council members commented that the traditional roles of operating room (OR) pharmacists have been focused on distribution, cost control, and limiting drug diversion, but that pharmacists need to take responsibility for broader oversight of the medication-use process and to be more engaged in the care of surgical patients. Council members believed there is a need for ASHP to look at the entire medication-use process holistically and consider how pharmacists should lead all elements of this highly complex process.

Pharmacovigilance. There is growing recognition that hospitals, health systems, and individual practitioners need to take more active roles in identifying and reporting patients' unintended, unexpected, and harmful responses to drugs used at normal therapeutic doses. Such events have traditionally been known as adverse drug reactions, which, by definition, are not medication errors. It is unlikely that an individual organization or practitioner will be able to detect a significant trend in such reactions, but signals can be identified through concerted efforts by practitioners and organizations to report observations to a central body that has the capability to aggregate and analyze data.

The Council believed that the pharmacy and risk management departments need to collaborate more closely in hospitals and health systems, with pharmacy having access to risk management data. It was suggested that the Council reexamine the issue of drug safety and pharmacovigilance next year, with emphasis on proposing revisions to ASHP policies, since the Institute of Medicine (IOM) is expected to recommend significant changes in terminology (e.g., the term “adverse drug reaction” is likely to be retired). The Council asked that, as new developments emerge from IOM, FDA, WHO, and other groups this year and next, ASHP provide sufficient coverage in the news, the *American Journal of Health-System Pharmacy* (AJHP), and educational programming.

Direct Patient Care. This discussion stemmed from a Recommendation during the 2007 ASHP House of Delegates and was related to the recently approved ASHP policy that by the year 2020, the completion of an ASHP-accredited postgraduate-year-one (PGY1) residency should be a requirement for all new college of pharmacy graduates who will be providing direct patient care. Some members of the House of Delegates believed that “direct patient care” as used here needs to be defined in order to clarify what future roles and responsibilities of pharmacists would necessitate a PGY1 residency. The Council discussed the need, rationale, and feasibility of developing such a definition.

The Council reviewed numerous ASHP policies and documents regarding patient care roles of pharmacists. These included the Requirement for Residency; Statement on Pharmaceutical Care; Guideline on Pharmacist-Conducted Patient Education and Counseling; Guidelines on a Standardized Method for Pharmaceutical Care; Guidelines on the Pharmacist's Role in the Development, Implementation, and Assessment of Critical Pathways; Guidelines on Documenting Pharmaceutical Care in Patient Medical Records; Statement on the Pharmacist's Role in Hospice and Palliative Care; Statement on the Pharmacist's Role in Primary Care; and policy 9820, Medication Administration by Pharmacists. Each of these documents addresses or alludes to direct patient care. One of the clearest and most specific examples resides in the ASHP Statement on Pharmaceutical Care: “the irrediscible unit of care is one pharmacist in a direct professional relationship with one patient.”

The consensus of the Council was that pharmacy is a patient care profession and pharmacists are patient care providers, and, as a result, everything pharmacists do should be considered direct patient care because of the direct or indirect impact on the patient.

Tobacco Use in the Media. The Council believed that existing policy 0713, Tobacco and Tobacco Products, sufficiently addresses the key issues associated with tobacco use and could be used in advocacy against the depiction of tobacco use in the media. The Council recommended that ASHP update its smoking cessation resource center to include recent studies that show a correlation between media depiction and smoking rates in teenagers.

Pharmacists' Bill of Rights. The Council discussed the rationale and need for developing an official pharmacists' bill of rights to ensure that pharmacists are able to provide safe and effective pharmaceutical care. The discussion was based on the nurses' bill of rights developed by a labor union representing nurses, the American Federation of State, County and Municipal Employees—United Nurses of America. The Council believed that current ASHP policy related to professionalism and pharmaceutical care and the code of ethics adequately address the issues described in the nurses' bill of rights, and do so in a way that reflects the core values of hospital and health-system pharmacy.

Drug-Related Devices. The Council discussed the key roles and responsibilities of pharmacists in this area and reviewed policy 8808, which was discontinued in 2007, as well as the Statement on drug delivery systems and devices. Council members believed that the current Statement sufficiently addresses the issues that were included in policy 8808 prior to discontinuation.

Radiopharmaceuticals. The Council requested that ASHP consider developing guidance on the role of pharmacists with radiopharmaceuticals, through enhanced educational programming and AJHP articles. The rationale for this request was that most pharmacists have limited knowledge about radiopharmaceuticals.

Pharmacogenomics. The Council requested that ASHP consider having the appropriate council discuss whether pharmacogenomic information should be included in official drug product labeling where applicable (e.g., warfarin and irinotecan). This request will be shared with the ASHP Task Force on Science.

Standardization of Bar Codes. Council members suggested that there are quality and scannability problems with some of the bar codes on pharmaceuticals. Council members asked ASHP to study this matter and determine if advocacy to FDA and the pharmaceutical industry is needed.

Patient's Own Devices and Other Medication-Enhanced Devices. Council members requested that ASHP develop guidance on medication delivery devices that are carried or worn by patients into the hospital (e.g., insulin pumps and pumps for pain management). The Council noted that organizations often do not have policy addressing what to do with devices brought in by patients, and that guidance is needed to help organizations, through their P&T committees, to develop such policy.

Saline Flushes. FDA recently reclassified saline flushes as devices; they were previously considered drugs. The Council suggested that ASHP address the fact that regardless of FDA's classification, saline flushes are still drugs.

White Paper on Pharmacy Technicians, 2002: Needed Changes Can No Longer Wait. The Council reviewed this document, which was endorsed by ASHP and a number of other pharmacy organizations. The Council's suggestions for revisions will be considered the next time the document is updated.
Appendix A—ASHP Statement on Pharmacy Services to the Emergency Department

Position

The American Society of Health-System Pharmacists (ASHP) believes every hospital pharmacy department should provide its emergency department (ED) with the pharmacy services that are necessary for safe and effective patient care. Although the nature of these services will vary with each institution’s needs and resources, the pharmacist’s role may include:

- Working with emergency physicians, emergency nurses, and other health care professionals to develop and monitor medication-use systems that promote safe and effective medication use in the ED, especially for high-risk patients and procedures,
- Collaborating with emergency physicians, emergency nurses, and other health care professionals to promote medication use in the ED that is evidence based and aligned with national quality indicators,
- Participating in the selection, implementation, and monitoring of technology utilized in the medication-use process,
- Providing direct patient care as part of the interdisciplinary emergency care team,
- Participating in or leading emergency-preparedness efforts and quality-improvement initiatives,
- Educating patients, caregivers, and health care professionals about safe and effective medication use, and
- Conducting or participating in ED-based research.

ASHP supports the expansion of pharmacy education and postgraduate residency training to include an emphasis on emergency care.

The purposes of this statement are to promote understanding of the pharmacist’s contributions to the care of patients in the ED and to suggest future roles for pharmacists in providing that care.

Background

EDs across the nation treat approximately 114 million patients annually.1 EDs are overcrowded because of a high percentage of uninsured patients, increased patient volume, increased complexity of patients presenting to the ED, and a hospital bed shortage that frequently results in the boarding of inpatients in the ED. The combination of interruptions, intense pressure, and a fast-paced environment can lead to medication errors and fewer error intercep-
tions.2 The Institute of Medicine (IOM) has estimated that as many as 98,000 people died each year as a result of medical errors and that adverse drug events (ADEs) occurred in 3.7% of hospitalizations.3 Hafner et al.4 reported a similar frequency of ADEs in the ED. Chin and colleagues5 found that 3.6% of patients received an inappropriate medication in the ED and 5.6% were prescribed an inappropriate medication at discharge.

Pharmacy services in the ED have been documented since the 1970s.6,7 These services initially focused on inventory control, cost containment, and participation on resuscitation teams but have expanded to include clinical pharmacy services.8 The effectiveness of clinical pharmacy services has been well documented in other settings. The participation of pharmacists in intensive care units and on internal medicine teams has improved patient outcomes by reducing preventable ADEs by 66% and 78%, respectively.9-11 Similar effectiveness with pharmacist participation on emergency medicine teams has also been documented.12 Despite this evidence, the 2005 ASHP national survey found that only 3.5% of the hospitals surveyed had a pharmacist assigned to the ED for any period of time, and only 5% had a formal policy requiring that pharmacists review and approve medication orders before administration in EDs.13

Pharmacy Services to the ED

All health care professionals share a commitment to and responsibility for providing safe and effective patient care. These shared objectives provide strong incentives for collaboration. Pharmacists and other health care professionals can collaborate in developing and monitoring medication-use systems that promote safe and effective medication use in the ED, including medication use in high-risk ED patients and procedures. Working together, pharmacists and other health care professionals can (1) ensure that medication use in the ED is evidence based, cost-effective, and adherent to national guidelines, (2) develop and implement emergency-preparedness plans and quality-improvement efforts, and (3) in many cases, foster the institution’s education and research initiatives. The department of pharmacy should assume a leadership role in ensuring these collaborations.

When making decisions regarding pharmacy services to the ED, hospital leadership should consider the ED’s need for medication therapy management services, medication-allergy assessment and clarification, medication-interaction assessment, reporting of and intervention on medication errors and ADEs, timely provision of drug information, and participation in formulary decision-making. Institutions should also keep in mind the Joint Commission’s pharmacist first-review requirement14 and National Patient Safety Goals15; the hospital’s quality indicators related to medication selec-
tion, timing, and delivery; the potential effects of patient flow and technology on medication safety in the ED; and contributions pharmacists can make to continuity of care from ED admission through hospital discharge.

Patient care. The IOM report Hospital-Based Emergency Care: At the Breaking Point recommends the inclusion of clinical pharmacists on the ED care team to ensure patients’ medication needs are appropriately met, lead system changes to reduce or eliminate medication errors, and evaluate the cost-effectiveness of medication therapy for the patient and hospital.1 As part of the interdisciplinary ED care team, pharmacists can provide care to critically ill patients by:

- Participating in resuscitation efforts,
- Providing consultative services that foster appropriate evidence-based medication selection,
- Providing consultation on patient-specific medication dosage and dosage adjustments,
- Providing drug information consultation to emergency physicians, emergency nurses, and other clinicians,
- Monitoring for patient allergies and drug interactions,
- Monitoring patient therapeutic responses (including laboratory values),
- Continuously assessing for and managing adverse drug reactions, and
- Gathering or reviewing medication histories and reconciling patients’ medications.

In addition to the above, pharmacists can provide care to ambula-
tory patients in the ED by:

- Modifying medication regimens based on collaborative-practice agreements for management of specific patient populations who return to ED;
- Providing vaccination screening, referral, and administration;
- Offering patient and caregiver education, including discharge counseling and follow-up; and
- Providing information on obtaining medications through patient assistance programs, drug funds, and samples.

The boarding of patients in the ED until an inpatient bed becomes available poses challenges for patients, caregivers, and health care professionals. The department of pharmacy should work with the health care professionals involved in the care of these patients to provide a seamless medication-use process.

Emergency-preparedness planning. ASHP believes that all hospital and health-system pharmacists must assertively exercise their responsibilities to prepare for and respond to disasters.16 ASHP has insisted that emergency response planners at the federal, regional, state, and local levels call upon pharmacists to participate in the full range of planning issues related to pharmaceuticals. Hospital emergency preparedness plans, including ED components, must be developed with the assistance of departments of pharmacy. Pharmacists should play a pivotal role in emergency preparedness planning and as a member of the health care team that provides care to victims. Because treatment of disaster victims almost always involves the use of pharmacologic agents, ensuring the efficacy and safety of the medication-use process is a natural role for pharmacists.17,18

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Quality-improvement initiatives. The department of pharmacy can collaborate with other health care professionals on a variety of quality-improvement initiatives in the ED, including:

- Guiding the development of evidence-based treatment protocols, algorithms, and clinical pathways that are congruent with nationally accepted practice guidelines and quality indicators.
- Assisting in the development, implementation, and assessment of various technologies used throughout the ED medication-use process.
- Conducting failure mode and effects analysis and root-cause analysis on error-prone aspects of the medication-use process.
- Participating in ED-based and hospitalwide committees (e.g., pharmacy and therapeutics, infection control, disaster) whose decisions affect medication use in the ED.
- Maintaining compliance with standards of national accrediting bodies, such as the Joint Commission, and
- Assisting in surveillance and reporting of adverse drug reactions.

Education. The pharmacy department should support the pharmacist’s role in providing education and information to health care professionals, patients, and the public in ED service areas. Specific activities could include:

- Conducting educational forums for health care professionals and students on topics such as emergency preparedness, disaster management, poisoning prevention and treatment, immunizations, and use of medications in the ED and emergency situations.
- Providing health literacy-sensitive education to patients and caregivers regarding medication use, disease state management, and prevention strategies, and
- Offering ED-based educational opportunities to pharmacy students and residents.

The ED offers an enormous number of services, activities, and opportunities to train future pharmacists in all aspects of the medication-use process. Students and residents could participate in longitudinal experiences in ED-based services such as clinics, community services (e.g., health fairs), and satellite pharmacies, studying topics as varied as cultural follow-up, ADE monitoring and reporting, or toxicology services. Introductory experiences could focus on student training on specific skills or competencies, such as taking medication histories, medication reconciliation, or discharge counseling. Residency training of pharmacists in emergency care would provide more rewarding educational experiences, foster pharmacist involvement in emergency medicine research, and ultimately improve the quality of patient care. Such residencies should meet ASPH-accredited residency quality standards. Achievement of the goals, objectives, and expected outcomes of such training would be supported by around-the-clock on-call clinical pharmacist services in the ED.

ED-based research. Research on and publications about ED pharmacy, though plentiful, usually focus on specific clinical settings, such as toxicology, drug interactions, and infectious disease epidemiology. The literature lacks a broad representation of the varied scope and range of ED pharmacy practices. ASPH believes that there should be more research on and publications regarding medication use in the ED and ED-based pharmacy activities. Studies that generate data on therapeutic, safety, humanistic, and economic outcomes of pharmacist-mediated process changes are urgently needed.

Professional Development of Pharmacists in Emergency Care

ASHP believes there should be an increase in the number of ED-based training opportunities for pharmacists, pharmacy students, and residents. Schools and colleges of pharmacy are encouraged to provide ED-based educational opportunities for students. Hospitals and health systems are encouraged to support ED-based educational programs that produce experts in the field. Postgraduate training of pharmacists will provide a pipeline of clinicians, educators, leaders, and scientists who are expert in and committed to quality emergency care.

Conclusion

Every pharmacy department should provide the ED with the pharmacy services required to ensure safe and effective patient care. These services must be tailored to match each institution’s needs and resources, so pharmacy departments must decide the best way to safely provide medications to their ED patients. ASPH supports the expansion of pharmacy education and postgraduate residency training to include emphasis on emergency care in order to develop an adequate supply of pharmacists trained to deliver these essential pharmacy services.

References


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Appendix B—ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System

Position
The American Society of Health-System Pharmacists (ASHP) believes that health systems should develop, organize, and administer a formulary system that follows the principles set forth below in order to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective medications.

Background
A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and/or treatment of disease and promotion of health.1 A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication use policies, important ancillary drug information, decision support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for health systems to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a health care organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

Pharmacy and Therapeutics Committee
To be effective, medication-use policies must have the concurrence of those involved in the medication-use process. Such consensus is achieved by developing those policies through a properly organized and representative pharmacy and therapeutics (P&T) committee or equivalent body (hereinafter, “the P&T committee”) and ensuring the approval of those policies by the organized medical staff. The P&T committee is composed of actively participating physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication-use process. Customarily, P&T member appointments are based on guidance from the medical staff.

The P&T committee should serve in an evaluative, educational, and advisory capacity to the medical staff and organizational administration in all matters pertaining to the use of medications (including investigational medications). The P&T committee is a policy-recommending body to the medical staff and the administration of the organization on matters related to the safe and therapeutic use of medications. The P&T committee is responsible to the medical staff as a whole, and its recommendations are subject to approval by the organized medical staff as well as the administrative approval process. The basic policies and procedures governing the P&T committee’s administration of the formulary system should be incorporated in the health system’s medical staff bylaws, medical staff rules and regulations, and other organizational policies as appropriate.

The overarching purposes of the P&T committee are policy development, communication and education, and formulary management.

Policy Development
The P&T committee formulates policies regarding evaluation, selection, diagnostic and therapeutic use, and monitoring of medications and medication-associated products and devices. The P&T committee should establish and assist in programs and procedures that ensure safe and effective medication therapy (e.g., clinical care plans, treatment guidelines, critical pathways, disease management protocols). Members of the P&T committee, or their representatives from appropriate specialties (including pharmacists), should participate in or direct the development and review of such programs or procedures, which should be kept current.

The P&T committee should participate in performance improvement activities related to procurement, prescribing, dispensing, administering, monitoring, and overall use of medications. The P&T committee should advise the institution, including the pharmacy department, in the implementation of effective medication distribution and control procedures, incorporating technological advances when appropriate. The P&T committee should initiate, direct, and review the results of medication-use evaluation programs to optimize medication use, and routinely monitor outcomes (economic, clinical, and humanistic) of formulary decisions. Medication-use evaluation should result in performance improvement initiatives to improve the medication-use process.

The P&T committee should take actions to prevent, monitor, and evaluate adverse drug reactions and medication errors in the health care setting, including those occurring with biologics and vaccines. Information from these activities should be disseminated to the appropriate health care personnel for informational and educational purposes (e.g., in newsletters, memoranda) and, when appropriate, to the Food and Drug Administration (FDA).

The P&T committee should establish clearly defined policies and procedures related to manufacturer sales representatives’ activities within the organization.

Communication and Education
The P&T committee ensures that mechanisms are in place to communicate with health care professionals, patients, and payers about all aspects of the formulary system, including changes made to the formulary or to policies and how formulary system decisions are made. The P&T committee also recommends or assigns in the formulation of educational programs designed to meet the needs of professional staff, patients, families, and caregivers on matters related to medications and medication use. The P&T committee should establish or plan suitable educational programs on matters related to medication use for staff involved in the care of patients and the use of medications.

Formulary Management
Health systems should develop, organize, and administer a formulary system that follows the principles set forth below in order to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective medications.

Formulary system. The P&T committee is responsible for administering the formulary system. Although the basic organization of each health care setting and its medical staff may influence the specific functions and scope of its P&T committee, key elements of a formulary system that should be included are evaluation of the clinical use of medications (including outcomes), development of policies and quality assurance activities for medication use administration, and evaluation and monitoring of adverse drug reactions and medication errors. The formulary system shall be endorsed by the medical staff based on the recommendations of the P&T committee. The medical staff should adapt the principles of the system to the needs of the particular organization and affiliated institutions and ambulatory care settings. The organization, often through the pharmacy department, should make certain that all personnel involved in the care of patients and the use of medications in all health-system components are informed about the existence of the formulary system, how to access the formulary, the procedures governing its operation, any changes in those procedures, and other necessary information (e.g., changes in drug product availability). This information may be further disseminated to other interested entities (e.g., affiliated managed care organizations).

Formulary. The P&T committee develops an evidence-based formulary of medications and medication-associated products accepted for use in the organization, provides for its timely revision and maintenance, and promotes the rational, clinically appropriate, safe, and cost-effective use of medications via guidelines, protocols, and other mechanisms. The P&T committee, on an ongoing basis, objectively appraises, evaluates, and selects medications for addition to or deletion from the formulary. The formulary is based on the best clinical evidence available and reflects the current clinical judgment of the medical staff, pharmacists, and other health care experts. The selection of items to be included in the formulary...
should be based on objective evaluation of their relative economic, clinical, and humanistic outcomes. The decisions should not be based solely on economic factors. The committee should identify potential safety concerns for each medication considered for inclusion in the formulary and ensure those safety concerns are addressed if the medication is added to the formulary or used in the health system.

The committee should minimize unnecessary duplication of the same basic drug type, drug entity, or drug product. Optimizing the number of drug entities and products available from the pharmacy can produce substantial patient-care and financial benefits. These benefits are greatly increased through the use of generic equivalents (drug products considered identical/equivalent by the FDA) and therapeutic equivalents (drug products differing in composition or in their basic drug entity that are considered to have very similar pharmacologic and therapeutic activities). The P&T committee must set forth policies and procedures governing the dispensing of generics and therapeutic equivalents.

The P&T committee, when considering formulary options, should evaluate coordination issues with local health care plans and other organizations’ formularies. At a minimum, appropriateness of therapeutic interchange should be evaluated for any formulary decisions that may conflict with known managed care or other health plan formularies.

The formulary should be published and updated regularly. The formulary should be readily available and accessible at all times either manually or electronically to all personnel involved in the care of patients and the use of medications. Medications should be identified in the formulary by generic name. Prescribers should be strongly encouraged to order medications by their generic names. The P&T committee must set forth policies and procedures governing the dispensing of generics and therapeutic equivalents.

The P&T committee should clearly define terminology related to formulary status of medications (e.g., formulary, nonformulary, not stocked at a given site, restricted by criteria specific to a given site), especially in multihospital organizations, and disseminate this information to health care professionals involved in the medication-use process. The P&T committee should establish a procedure for appraisal and use by the medical staff of medications not included in the formulary (i.e., nonformulary medication use).

The pharmacist shall be responsible for specifications for the quality, quantity, and source of supply of all medications, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients.

Conclusion

ASHP believes that medication-use policies should be developed and implemented in organized health care systems to promote the rational, evidence-based, clinically appropriate, safe, and cost-effective use of medications. The P&T committee of health systems should develop, organize, and administer a formulary system that follows the principles set forth in this statement in order to optimize patient care.

References


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Board of Directors Report on the Council on Public Policy

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

Sheila L. Mitchell, Board Liaison

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Donna S. Wall (Indiana)
Sarah E. Yost (Texas)
Brian M. Meyer, Secretary

Policy Recommendations

A. Education, Prevention, and Enforcement Concerning Workplace Violence

To advocate that federal, state, and local governments recognize the risks and consequences of workplace violence in the pharmacy community and enact appropriate criminal penalties; further,

To collaborate with federal, state, and local law enforcement and other government authorities on methods for early detection and prevention of workplace violence: further;

To encourage all workplace environments to develop and implement a policy for pharmacy personnel that (1) educates about prevention and deterrence of workplace violence, (2) identifies escalating situations that can lead to violence and instructs employees on protection and self-defense, (3) provides continued support and care to heal personnel who were directly or indirectly involved in an incident of workplace violence; further,

To encourage the health care community to develop and maintain a communication network to share information about incidents of potential and real workplace violence.

B. Regulation of Dietary Supplements

To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling and patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; (3) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement
manufacturers to report suspected adverse reactions to
the FDA; further,

To oppose direct-to-consumer advertising of dietary
supplements unless the following criteria are met: (1)
federal laws are amended to include all the requirements
described above to ensure that dietary supplements
are safe and effective; (2) evidence-based information
regarding safety and efficacy is provided in a format that
allows for informed decision-making by the consumer;
(3) the advertising includes a recommendation to con-
sult with a health care professional before initiating
use; (4) any known warnings or precautions regard-
ing dietary supplement–medication interactions or
dietary supplement–disease interactions are provided
as part of the advertising; and (5) the advertising is
educational in nature and includes pharmacists as a
source of information.

(Note: This policy would supersede ASHP policy
0718.)

Background

The Council considered several Recommendations from the 2007
meeting of the ASHP House of Delegates and developed a revision to
policy 0718. The Recommendations sought to include the following
issues in a dietary supplement policy: ingredient labeling, provision
of written patient information, content and purity, testing by the
United States Pharmacopeia, and direct-to-consumer advertising.
In developing the proposed policy, the Council was guided by the
ASHP Statement on the Use of Dietary Supplements.

The proposed policy addresses two issues. First, it states the need
for the Food and Drug Administration (FDA) to have authority to
require safety and efficacy testing for dietary supplements, require la-
beling and information about the content of the product and its safe
use, and require manufacturers to report suspected adverse reactions
to FDA. Second, it clearly states opposition to direct-to-consumer
advertising of dietary supplements unless the specified criteria are
met (including changes in federal law granting FDA the necessary
authority); this is a change from existing policy 0718, which sup-
sports direct-to-consumer advertising only if certain specified criteria
are met. In developing this position of opposition, the Council and
Board were guided by delegate Recommendations and discussion
during the 2007 House of Delegates session. This policy addresses all
of the delegate Recommendations, including USP testing.

Just after the House of Delegates Meeting in June 2007, FDA an-
nounced final regulations requiring current Good Manufacturing
Practices that include testing ingredients and the final product.
The Council noted that the ASHP Statement on the Use of Dietary
Supplements should be updated to reflect changes and initiatives
by FDA with respect to current good manufacturing practices and
adverse event reporting.

Policy 0718 reads as follows:

To support direct-to-consumer advertising of dietary supplements
only when it is educational in nature and includes pharmacists
as a source of information; further,

To support direct-to-consumer advertising of dietary supple-
ments only when it includes (1) evidence-based information
regarding safety and efficacy in a format that allows for informed
decision-making by the consumer; (2) a clear disclaimer that the
product was not evaluated by FDA for safety and effectiveness;
(3) a recommendation to consult with a health care professional
before initiating use; and (4) any known warnings or precautions
regarding dietary supplement–medication interactions or dietary
supplement–disease interactions; further,

To support the development of legislation or regulation requiring
that dietary supplement advertising prominently state risks and
intended benefits of a product that consumers should discuss
with their licensed health care professional.

C. Appropriate Staffing Levels

To advocate that pharmacists at each practice site es-

tablish the site's appropriate pharmacist and technician
staffing levels on the basis of patient safety consider-
ations, taking into account factors such as (1) acuity of
care, (2) breadth of services, (3) historical safety data,
and (4) results of research on the relationship between
staffing patterns and patient safety; further,

To advocate that regulatory bodies not mandate specific,
uniform pharmacy personnel ratios but rather ensure
that site-specific staffing levels optimize patient safety;

To encourage additional research on the relationship be-
tween pharmacy staffing patterns and patient safety.

(Note: This policy would supersede ASHP policy
0717.)

Background

The Council revised policy 0717 on the basis of a Recommenda-
tion from the 2007 session of the House of Delegates. In its review,
the Council found policy 0717 to be appropriate but wanted to add
language that described the purpose of appropriate staffing levels and
the importance of board of pharmacy collaboration with individual
practicing pharmacists.

The Council noted and the Board agreed that the purpose of
any staffing level should be to ensure quality patient care. The
Council and Board specified some of the factors to be considered in
developing an appropriate staffing level and noted that boards of
pharmacy should not mandate a specific ratio for a specific practice
setting. Rather, pharmacists should collaborate with their board of
pharmacy to determine the appropriate staffing level for achieving
quality patient care. Such collaboration would allow flexibility to
base staffing levels on factors specific to the practice setting, such as
acuity level, services provided, and safety data. The Council and
Board recognized the legitimate need for boards of pharmacy to as-
sure minimum standards of practice to protect the public health. The
Council and Board acknowledged the need for additional research
on staffing models to support staffing levels that provide safe and
effective patient care.

Policy 0717 reads as follows:

To advocate that pharmacist-to-technician and pharmacist-to-
patient ratios be determined by local institutions on the basis of
acuity of care, breadth of services, quality improvement processes,
and historical data; further,

To encourage additional research on staffing models that are
based on best practices in order to provide safe and effective
patient care.

D. Medicare Prescription Drug Benefit

To strongly advocate a fully funded prescription drug
program for eligible Medicare beneficiaries that main-
tains continuity of care and ensures the best use of
medications; further,

To advocate that essential requirements in the program
include (1) appropriate product reimbursement; (2)
affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services; based on a study of those costs; (4) appropriate cover age and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient’s choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

(Note: **Fully funded** means the federal government will make adequate funds available to fully cover the Medicare program’s share of prescription drug program costs; **eligible** means the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.)

(Note: This policy would supersede ASHP policy 0721.)

**Background**

This is a proposed revision to policy 0721 in response to a recommendation by a Delegate concerned about the impact of "transparency of drug costs" for determining appropriate product reimbursement. That phrase was deleted in the proposed policy to recognize that contracts between prescription drug plans and the manufacturer are often proprietary. The Council believed and the Board concurred that requiring "transparency" would have an impact on these contracts and ultimately on the cost to consumers.

Policy 0721 reads as follows:

To strongly advocate a fully funded prescription drug program for eligible Medicare beneficiaries that maintains continuity of care and ensures the best use of medications; further,

To advocate that essential requirements in the program include (1) appropriate product reimbursement based on transparency of drug costs; (2) affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services, based on a study of those costs; (4) appropriate coverage and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient’s choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

(Note: **Fully funded** means the federal government will make adequate funds available to fully cover the Medicare program’s share of prescription drug program costs; **eligible** means the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.)

**E. Federal Review of Anticompetitive Practices by Drug Product Manufacturers**

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

2. To encourage appropriate federal review of these practices.

(Note: This policy would supersede ASHP policy 0520.)

**F. Confidentiality of Patient Health Care Information**

1. To approve the ASHP Statement on Confidentiality of Patient Health Care Information (Appendix A).

(Note: This statement would supersede the 1999 version of the document.)

**Background**

The Council approved revisions to the Statement on Confidentiality of Patient Health Care Information. The Statement was first approved in 1999 and has been revised to reflect current practice as well as provisions of the Health Insurance Portability and Accountability Act and its implementing regulations. The Council and Board believed that this Statement continues to be useful to members in complying with privacy laws while maintaining access to patient information to provide quality care.

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**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 were found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Role of Licensing, Credentialing, and Privileging in Collaborative Drug Therapy (0318)

- Drug Product Shortages (0319)
- Licensure for Pharmacy Graduates of Foreign Schools (0323)
- Public Funding for Pharmacy Residency Training (0325)
- Collaborative Drug Therapy Management (9812)
- Regulation of Automated Drug Distribution Systems (9813)
- Health Care Reform (9303)

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Other Council Activity

Pharmacy Services, Practice Models, and Innovative Technology in Underserved Areas. In discussing pharmacy services in underserved areas, the Council referred to existing policies 0218, Pharmacist Recruitment and Retention, and 0503, Critical-Access, Small, and Rural Hospitals. The Council discussed the need to promote quality pharmacy services, innovative practice models, and the use of technology throughout the nation’s health care system and identified the unique challenges in serving patients in rural and underserved locations.

Council members noted the need to provide new and current practitioners with incentives to practice in these settings. The Council believed that eligibility for loan forgiveness for pharmacists serving in designated rural and underserved locations would be an important part of the solution to providing quality services.

The Council identified opportunities for policy and program development in this area. Council members noted that funding from public and private sources should be used to research and develop innovative practice models to serve patients in these areas. Council members observed that hospitals that are small, rural, or located in underserved areas are unable to pass on labor costs and compete for pharmacists from other locations and practice settings. Possible innovations in residency programs include offering residents full pay for practicing in small, rural, or underserved locations and providing incentives for creating innovative preceptor arrangements. Such innovations could be supported initially by public or private funding, with transition to self-sufficient funding after a set period of time. Student experiential rotations were mentioned by the Council as an opportunity to explore future practice opportunities while helping provide patient care services.

Council members also noted the need for laws and regulations that would enable the provision of services through pharmacist remote supervision of a technician and would thereby serve patients in these underserved areas. Council members noted that existing policy 0716, Regulation of Telepharmacy Services, addresses this need.

In addition, the Council believed there was merit in further discussion of this issue by the Section of Pharmacy Informatics in regard to the use of innovative technology to provide patient care services for remote, underserved locations. An analysis of existing technology applications and how they could overcome barriers to providing care would be useful as the Council and ASHP pursue advocacy in this area. As policy options are considered, the goal should be to develop solutions that benefit patients, pharmacists, and policymakers.

Advanced Practice Licensure. The Council discussed the concept of an advanced practice license for pharmacists that would be issued by state boards of pharmacy. A license would be needed for third-party payers to authorize payment for high-level drug therapy management. Council members also discussed requiring residency training or Board of Pharmaceutical Specialties certification as a prerequisite to advanced practice licensure and authorization of payment for high-level drug therapy management.

The Council did not believe there was a need to develop a policy advocating advanced practice licensure. However, the Council acknowledged that boards of pharmacy may require additional credentials for pharmacists who engage in collaborative drug therapy management or medication therapy management. The Council was unaware of any outcomes research documenting the need for an advanced license or supporting improved outcomes of care provided by pharmacists with any particular certification or training. The Council discussed the need to revise existing policies 0318, Role of Licensure, Credentialing, and Privileging in Collaborative Drug Therapy Management, and 9812, Collaborative Drug Therapy Management. The Council also discussed the Medication Therapy Management Services Definition and Program Criteria, a consensus definition approved by 11 national pharmacy organizations in 2004.

The Council voted to reaffirm the two existing policies but decided to revise them next year to address state board requirements for additional credentials to engage in high-level drug therapy management. The Council requested that research be done to determine if improved patient outcomes have been documented as a result of care provided by pharmacists with advanced training or certification.

The next revisions in these policies would also further define and possibly differentiate between collaborative drug therapy management and medication therapy management.

Compensation for Consultative Services. In response to a recommendation from the 2007 House of Delegates concerning payment for consultative services to remote and inpatient locations, the Council reviewed policy 0207, Product Reimbursement and Pharmacist Compensation, and the ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems. Council members believed that these two documents addressed the issue of compensation for services but that they needed to be harmonized and updated. Council members also noted that the title of policy 0207 should include the idea of compensation for pharmacist services. The Council noted that sessions at the recent Summer Meeting on the use of Current Procedural Terminology (CPT) codes for pharmacist services reimbursement were a good example of programming to increase member awareness. Additional coverage by ASHP of innovative reimbursement by Medicaid in North Carolina and Minnesota was also suggested.

Patient’s Right to Unapproved Medications. The Council discussed a recent federal court case, Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, regarding a patient’s right to an investigational drug and FDA’s policy on investigational drugs and compassionate-use programs. The Council believed FDA’s mission to protect the public health and its existing patient access programs provided sufficient balance with the patient’s right to unapproved drugs. The Council believed that existing policy 0012, FDA’s Public Health Mission, will provide sufficient guidance to ASHP regarding its advocacy on this issue.

Access to Patient Information during Emergencies. The Council reviewed the RX Response program designed to prepare the health care community (including pharmacies) for natural and man-made emergencies. The Council urged ASHP’s continued involvement in these programs to ensure hospital pharmacist access to patient information when it is not readily available. The Council noted that the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness was still relevant. However, it noted that any revision of the document should also include advice to patients, to underscore the responsibility of patients in emergency preparedness.

Universal Health Coverage: State Initiatives and Presidential Platforms. The Council reviewed current initiatives by Massachusetts, California, and other states to move toward universal coverage for their residents. The Council also considered the initial descriptions of the platforms of the candidates running for president of the United States. The Council reviewed policy 0512, Full Health Insurance Coverage, as well as the ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems. Council members thought that policy 0512 was still relevant but believed the Statement, approved in 1992, needed to be updated. Since 1992, a Medicare prescription drug benefit has been enacted, as well as other major health reforms, particularly in the area of information technology and privacy.

The Council believed the issue of coverage for the uninsured and universal coverage should be on the agenda of ASHP state affiliates, since public policy experimentation will take place first at the state level. Council members believed that state affiliates could contribute to solutions and thereby demonstrate their credibility to state policymakers. Council members suggested informing the ASHP membership about presidential candidates’ positions as more details and analysis becomes available. Finally, the Council noted the need for pharmacists to be exposed to the health care policymaking process so that they will become actively engaged and influence the policy debate.

White Paper on Technicians. The Council reviewed this document, which was endorsed by ASHP and a number of other pharmacy organizations. The Council’s suggestions for revisions will be considered the next time the document is updated.
Appendix A—ASHP Statement on Confidentiality of Patient Health Care Information

The American Society of Health-System Pharmacists believes all medical information is sensitive and should be given the utmost protection. ASHP supports the adoption into federal law of a minimum standard for protection of individually identifiable patient health information, while states should retain the ability to adopt standards that are more stringent than federal law.

ASHP believes patients should have the right to access and review their medical records and the ability to correct factual errors in those records. Patients should also have the right to know who has access to their medical records and to authorize how their medical information will be used.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires health systems to have written policies and procedures in place to guard against the unauthorized collection, use, or disclosure of individually identifiable patient health information and provide notice of such policies to their patients. All health-system personnel should be trained to understand and comply with those privacy standards.

ASHP strongly believes that pharmacists must have access to patient health records in order to provide quality care and ensure the safe use of medications. Within health systems, all authorized practitioners should be encouraged to communicate freely with each other while maintaining patient confidentiality and privacy. This includes pharmacists practicing across the continuum of practice settings in order to maintain continuity of care. Pharmacists recognize that with access to the patient’s health record comes the pharmacist’s professional responsibility to safeguard the patient’s rights to privacy and confidentiality. Uniquely identifiable patient information should not be exchanged without the patient’s authorization for any reason not directly related to treatment, payment, health care operations, or research conducted under an appropriately constituted Institutional Review Board (IRB). ASHP advocates strict governmental protections, with appropriate civil or criminal penalties for violations, to prevent disclosure of individually identifiable patient information outside the health system (i.e., to an unauthorized third party) for any purposes not directly related to treatment, payment, health care operations, or research conducted under an appropriately constituted IRB.

Pharmacists participate extensively in research on drugs. ASHP believes all research data must be recorded and stored in such a way that the subjects’ rights of privacy and confidentiality are protected. IRBs have a responsibility to determine when informed consent is necessary and to establish procedures for obtaining informed consent. Patients should receive a statement describing the parties that may have access to patient-identifiable information (e.g., institutional personnel, business associates, researchers, personnel from study sponsors, or employees of government agencies that monitor compliance with regulations). Patient authorization requirements under the privacy regulations of HIPAA must be followed, and patients always have the right to withdraw their consent at any time.

ASHP believes there is no potential for a breach of patient confidentiality when patient information is aggregated for use in legitimate research or statistical measurement and is not uniquely identifiable. Therefore, specific authorization by individual patients for access to this information is not needed.

ASHP believes pharmacy residency programs and other training programs must implement policies and procedures to ensure the confidentiality of patient medical records while allowing pharmacy students and residents access to these records in the course of their training and presentation of their research.

Approved by the ASHP Board of Directors on February 22, 2008.

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Board of Directors Report on the Council on Therapeutics

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

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Cynthia Reilly, Secretary

Policy Recommendations

A. ASHP Statement on Criteria for an Intermediate Category of Drug Products

1. To approve the ASHP Statement on Criteria for an Intermediate Category of Drug Products (Appendix A).

Background
In 2002, ASHP approved policy 0220, Intermediate Category of Drugs:

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

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

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

1. Drug products appropriate for this intermediate category would be identified through the advice of pharmacists, physicians, and other licensed health professionals who are authorized to prescribe medications, on the basis of the medical conditions to be treated and potential adverse effects (as indicated in FDA-approved labeling);
2. Pharmacists would be able to provide drugs in this intermediate category directly to patients without a prescription, on the basis of appropriate assessment and professional consultation;
3. Licensed health professionals who currently have prescribing authority would continue to have the ability to prescribe medications in this intermediate category; and
4. Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reporting would be collected to help determine a drug product’s eventual movement to nonprescription status, return to prescription-only status, or continuation in the intermediate category.

This policy was reviewed in 2006 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate. In September 2005, the Commission on Therapeutics recommend that ASHP develop a statement describing criteria for determining appropriate medications for inclusion in the proposed intermediate category. The Commission and Board of Directors believed that this statement could provide the Food and Drug Administration (FDA) with a framework for ensuring the safety and effectiveness of the proposed category of drug products. In November 2007, FDA held a public workshop to obtain stakeholder comments regarding the establishment of a behind-the-counter, or BCT, category of drug products. At that meeting, FDA sought input on characteristics of
drugs appropriate for the proposed category and on the potential impact of this category on patient access to treatment; overall costs to patients, health systems, and health insurers; and pharmacy and medical practice models. ASHP's detailed comment to FDA on conditions necessary for optimizing the use of the intermediate category of drug products, including a call for the development of alternative reimbursement models, is available at www.ashp.org/6_adsip/docs/files/advocacy/ASHP_Written_Comments_Final.pdf.

B. Pharmacist's Leadership Role in Anticoagulation Therapy Management

1. To advocate that pharmacists provide leadership in the interdisciplinary development, implementation, maintenance, effectiveness monitoring, and assurance of continuity of care of anticoagulation management programs; further,

2. To advocate that pharmacists be responsible for coordinating the individualized care of patients within anticoagulation management programs; further,

3. To encourage pharmacists who participate in anticoagulation programs to educate patients, caregivers, prescribers, and staff about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, and recommended laboratory testing and other monitoring.

Background

The Joint Commission 2008 national patient safety goals for hospitals include a requirement for reducing the likelihood of harm associated with anticoagulant therapy. Health care facilities are instructed to assign leadership for ensuring compliance with this requirement, standardize therapeutic practices and protocols, establish monitoring procedures and a drug-food interaction program, individualize care for each patient receiving these treatments, and provide education on the appropriate management of these patients.

The Council and the Board of Directors agreed that pharmacists play a central role in coordinating the management of anticoagulant therapies within health systems and believed that a policy would support this important role.

C. Generic Substitution of Narrow Therapeutic Index Drugs

1. To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

2. To oppose a blanket restriction on generic substitution for any medication or medication class in the absence of well-designed, independent studies that provide evidence of inferior efficacy or safety of the generic drug product compared with the innovator.

Background

Recent state-level attempts to restrict generic substitution of antiepileptic therapies through passage of legislation or regulation (e.g., in Illinois, Wisconsin, and Texas) would require pharmacists to obtain explicit permission from physicians for generic substitution of these drug products. Supporters of these legislative actions believe that substitution of generic antiepileptic therapies may cause adverse effects and breakthrough seizures, which could result in serious harm or death. FDA has stated that demonstrated variance in serum drug concentrations between generic and innovator products is too small to make a clinically significant difference in patient response to therapy.

The Council discussed the proposed state regulations within the larger context of the FDA approval process for generic drugs and the potential for patient harm with substitution of narrow therapeutic index drugs (e.g., warfarin, levothyroxine). The Council noted that the limited evidence used to support the legislative efforts consisted of anecdotal patient reports and small-scale studies. The Council concluded that these studies were not well-designed and did not assess factors such as adherence, which would have affected the patients' response to therapy. In addition, the extent of variability seen in these studies would be expected because of inherent differences in patient characteristics. It was also noted that therapeutic drug monitoring for the newer antiepileptic drugs is not common in clinical practice. Believing that the current system that allows prescribers to write "dispense as written" was sufficient to allow individual prescriber preference, the Council opposed a blanket restriction on substitution that is based on drug class and not supported by evidence.

D. Dietary Supplements Containing Ephedrine Alkaloids

1. To discontinue ASHP policy 0302, which reads:

2. To support a ban on the manufacture and sale of dietary supplements containing ephedrine alkaloids because (1) ephedrine alkaloids pose a significant risk of illness and injury, (2) changes in product labeling are not adequate to protect the public from these dangers, (3) the use of these products represents significant expenditures for a health-related remedy of unsubstantiated value, and (4) other safe and effective interventions are available for all common uses of these products.

Background

This policy was recommended by the Commission on Therapeutics, approved by the Board of Directors in 2003, and adopted by the House of Delegates on June 1, 2003, in response to safety concerns about dietary supplements containing ephedrine alkaloids. At that time, products containing ephedrine alkaloids were widely marketed as weight-control and performance- and energy-enhancing products. Safety reports linked their use to significant circulatory system adverse events, including heart attack and stroke. The Commission advocated a ban on the sale of products containing ephedrine alkaloids, stating that proposed changes in product labeling would not adequately protect the public from danger. The Commission also noted that evidence supporting the therapeutic value of ephedrine alkaloids was lacking and that safer and more effective therapies were available for all conditions for which this product was commonly used. Subsequently, FDA banned the use of ephedrine alkaloids in dietary supplements, effective in April 2004.

The Council noted that there are occasional reports of adulteration of products with ephedrine alkaloids despite the FDA ban, and that other substances with safety concerns (e.g., bitter orange) are now used to replicate the effects of ephedrine. However, the Council believed that the broader ASHP Statement on the Use of Dietary Supplements met the intent of this more specific policy. Therefore, the Council believed that this policy is no longer necessary.
Board Actions


To discontinue the ASHP Therapeutic Position Statement on the Use of the International Normalized Ratio System to Monitor Oral Anticoagulant Therapy.

This Therapeutic Position Statement (TPS) was approved by the Board of Directors in November 1994 and published in the American Journal of Health-System Pharmacy (AJHP) in March 1995. The statement was subsequently reviewed by the Commission on Therapeutics and Board of Directors in 2002 and found to still be appropriate. Development of the statement was sparked by changes in the source for thromboplastin reagents in the 1970s and 1980s that resulted in a substantial decrease in the sensitivity of this test and decreased measured prothrombin time (PT) values. The substitution was not widely recognized by practitioners; this led to unnecessary increases in doses of warfarin in response to falsely decreased PTs. In 1985, the World Health Organization developed and recommended use of the international normalized ratio (INR) system to measure and account for the responsiveness of each batch of reagents. The goal of this TPS was to address ongoing practice variances in measuring response to anticoagulant therapy.

The Council believed that this TPS should be discontinued because the process for monitoring INR advocated in this document has now become the standard of care. In addition, the Council believed that pharmacists’ information needs extend beyond the scope of this document and suggested that ASHP pursue a more comprehensive approach to assist members in optimizing anticoagulation management. For these reasons, the Council did not support a revision of this document.

ASHP Therapeutic Position Statement on the Use of Beta-Blockers in Survivors of Acute Myocardial Infarction. The Council recommended and the Board voted

To discontinue the ASHP Therapeutic Position Statement on the Use of Beta-Blockers in Survivors of Acute Myocardial Infarction.

This TPS was approved by the Board of Directors in June 2002 and published in AJHP in November 2002. The purpose of this statement was to address underutilization of beta-blockers, which strong and consistent evidence has shown reduce morbidity and mortality in patients surviving a myocardial infarction (MI).

In May 2007, the National Committee for Quality Assurance (NCQA) announced that it would no longer report beta-blocker usage in survivors of acute MI as a quality measure, stating that it was no longer necessary because of the high percentage of these patients who receive a prescription for beta-blockers within seven days of hospital discharge; NCQA had used this measure to evaluate managed health care plans since 1996. Statistics from hospitals reporting to the U.S. Department of Health and Human Services Hospital Compare website from April 2006 through March 2007 show that 88% of heart attack patients received a beta-blocker at admission and that 90% received a beta-blocker at discharge.

The Council stated that national quality measures (e.g., Centers for Medicare and Medicaid Services), measures by private insurers (e.g., Blue Cross Blue Shield), and the ongoing education of health care providers have significantly closed the gap that this TPS was developed to address. The Council also noted that the use of beta-blockers is now routinely included in clinical pathways (e.g., treatment protocols, electronic medication order entry systems) and stated that reimbursement models will continue to close the gap. For these reasons, the Council believed that the TPS is no longer necessary and that ASHP resources would be better utilized to develop guideline documents or education that addresses “bundles” of care for quality measures (i.e., not just beta-blockers, but also aspirin, angiotensin-converting enzyme inhibitors, and other therapies recommended following an MI).

Clinical Practice Guidelines for Sedation, Analgesia, and Neuromuscular Blockade in Critically Ill Patients. The Council recommended and the Board voted

To collaborate with the Society of Critical Care Medicine in the revision of the clinical practice guidelines for sedation, analgesia, and neuromuscular blockade of the critically ill adult.

The Council reviewed two guidelines and an executive summary related to the use of sedatives, analgesics, and neuromuscular receptor-blocking agents in critically ill patients. The guidelines were developed through the Task Force of the American College of Critical Care Medicine of the Society of Critical Care Medicine (SCCM), in collaboration with ASHP and in alliance with the American College of Chest Physicians. The documents—“Sedation, Analgesia, and Neuromuscular Blockade of the Critically Ill Adult: Revised Clinical Practice Guidelines for 2002,” “Clinical Practice Guidelines for Sustained Use of Neuromuscular Blockade in the Adult Critically Ill Patient,” and “Clinical Practice Guidelines for the Sustained Use of Sedatives and Analgesics in the Critically Ill Adult”—were approved by the Board of Directors in November 2001 and published in AJHP in January 2002.

The Council and the Board of Directors recommended that ASHP collaborate with SCCM in revising these guidelines, which are valuable resources for ASHP members who practice in critical care, as well as for those who care for patients transitioning in and out of critical care settings and other care units where patients might require sedation. The high cost of these therapies and the accreditation standards set by the Joint Commission are additional factors that make these guidelines of great interest to all pharmacy practitioners and other disciplines. For these reasons, the Council believed that ASHP should participate in the revision of the complete set of guidelines.

Other Council Activity

Management of Anticoagulation Therapies. The Council supported the development of a guideline on the management of anticoagulation therapies. In 2004, the American College of Chest Physicians (ACCP) provided guidance to clinicians in the multidisciplinary Seventh American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy: Evidence-Based Guidelines, and revisions to those guidelines are currently in process. The importance of anticoagulation therapy management was highlighted by the Joint Commission’s 2008 national patient safety goals, which include a requirement for reducing the chance of harm associated with these therapies. The Council suggested that pharmacists would find value in concise guidelines that address gaps between the ACCP guidelines and current practice. The Board of Directors recommended that ASHP collaborate with ACCP on development of the proposed guideline.

Safety and Effectiveness of Antidepressant Use in Pediatric, Adolescent, and Young Adult Patients. The Council reviewed the 2004 and 2007 FDA-issued black box warnings about increased suicidality with antidepressant use in pediatric, adole-
cent, and young adult patients. This labeling change was based on studies demonstrating that the incidence of suicidal thoughts was increased in patients treated with antidepressants. The Council also reflected on the existing evidence and noted that the Centers for Disease Control and Prevention had released statistics in September 2007 that showed the suicide rate in individuals ages 10 to 24 years increased by 8% between 2003 and 2004—the largest increase in more than 15 years.

The Council recognized that absolute cause-and-effect relationships among issuance of the black box warning, declining antidepressant use, and suicide rates could not be established, noting that the black box warnings were issued on the basis of a retrospective analysis of data from efficacy studies that were not designed to assess safety. The Council concluded that there is conflicting evidence about whether antidepressants increase or decrease suicidality and that additional postmarketing studies are needed to determine the safety of these drugs in pediatric, adolescent, and young adult patients. The Council believed that an ASHP statement that emphasized strategies for ensuring the safe use of these therapies in these patient populations would assist pharmacists in the management of these therapies while the evidence continues to accrue.

**Preferential Use of Metronidazole for the Treatment of Clostridium difficile-Associated Disease.** The Council reviewed the ASHP Therapeutic Position Statement on the Preferential Use of Metronidazole for the Treatment of Clostridium difficile-Associated Disease. The statement was approved by the Board of Directors on April 1998 and published in AHP in July 1998. The document was subsequently reviewed by the Commission on Therapeutics and Board of Directors in 2002 and found to still be appropriate. The 2007 Council believed that this TPS provides an important resource to clinicians and recommended that it be revised to address the emergence of new strains of C. difficile. The current TPS should be kept active while the revision is in process. The Council suggested that ASHP pursue collaboration with the Infectious Diseases Society of America or the Society of Infectious Diseases Pharmacists to develop or endorse this document.

**Use of Nonsteroidal Anti-inflammatory Agents for Managing Acute Pain.** The Council recommended that ASHP not develop an ASHP Therapeutic Position Statement on Nonsteroidal Anti-inflammatory Agents for Managing Acute Pain. This TPS was initially recommended as a therapeutic guideline on chronic pain by the Commission on Therapeutics in 2003 and was revised to a TPS on the management of acute pain in 2004. The impetus for developing this guidance document was to address safety issues with the cyclooxygenase-2 (COX-2) inhibitors and concerns about overuse of those drugs. Since that time, two of those drugs have been withdrawn from the market and safety information has been widely distributed. The Council believed that current usage patterns of the remaining COX-2 inhibitors are largely consistent with appropriate use. For these reasons, the Council recommended that development of this document not be pursued.

**Clinician Access to and Use of Safety Information from Postmarketing Surveillance.** Recent market withdrawal of several widely used drugs (e.g., rofecoxib, tegaserod) and concerns about increased mortality with some therapies (e.g., rosiglitazone, erythropoiesis-stimulating agents) have highlighted the need for increased postmarketing surveillance to improve drug safety. The Council noted that several efforts are under way to enhance drug safety, including ongoing research funded by the Agency for Healthcare Research and Quality and collaborations among research and academic centers (e.g., Research on Adverse Drug Events and Reports [RADAR]). In addition, provisions within the reauthorized Prescription Drug User Fee Act give FDA additional authority to request and conduct postmarketing safety studies. The Council believed that these activities were all positive steps toward improving drug safety.

The Council encouraged ASHP to look for future opportunities for comment and involvement as FDA establishes the framework for identification and analysis of postmarketing drug information. The Council believed that safety information should be provided in a timely and useful fashion but that FDA should be advised to use caution to avoid publicity of or use of safety data that could lead to public hysteria or to manipulation of these data by manufacturers for marketing purposes. ASHP was encouraged to keep members informed about the importance and status of this initiative through news releases and other communication vehicles.

**Safe Use of Medications in the Elderly.** The Council reviewed systems used to identify potentially inappropriate prescribing for the elderly (age 65 years or older), such as the Beers criteria and Assessing Care of Vulnerable Elders (ACOVE). While acknowledging the good intent of these measures, the Council noted that these systems and the studies that have assessed them measure quality of care in nursing homes and have not been validated in hospitals and other settings. It was noted that the Beers criteria measure only whether the patient received the treatment, not the outcome or whether the patient was harmed by that treatment. The current systems also do not distinguish between chronological age and functional age (e.g., declines in creatinine clearance) and do not account for the additive effects of polypharmacy that can make the elderly more vulnerable to falls. The Council believed that the evidence is needed to develop or endorse this document.

**Evidence-Based Use of Erythropoiesis-stimulating Agents in Chronic Kidney Disease.** The Council reviewed information on recent safety concerns about erythropoiesis-stimulating agents ( ESA s); FDA imposed a black box warning for these therapies on the basis of evidence that high hemoglobin levels led to increased mortality in oncology patients. Similar concerns exist with the use of these therapies for patients with chronic kidney disease. The Council expressed concern that these drugs are overused and used inappropriately, noting the use of off-label doses and dosing frequencies and inconsistent use of required adjuvant therapies (e.g., iron). The Council emphasized that all pharmacists—regardless of specialty—must have an understanding of these therapies because most patients will experience kidney function decline or failure during their lifetime.

The Council suggested that ASHP support the upcoming revision to the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI) Clinical Practice Guidelines by incorporating a section of the guideline through ASHP publishing vehicles and educational programs. The Council also noted that there is limited evidence on the use of these agents in the inpatient setting and encouraged ASHP members, the National Kidney Foundation, and members of American College of Clinical Pharmacy to collaborate on additional studies.

**Patients’ Rights to Unapproved Medications and FDA’s Public Health Mission.** The Council reviewed events related to litigation concerning whether patients excluded from a clinical trial for an investigational drug have a constitutional right to obtain that drug prior to its approval by FDA. In 2006, a three-judge panel for U.S. Court of Appeals for the District of Columbia Circuit ruled in favor of the Abigail Alliance for Better Access to Developmental Drugs in a decision finding that, under the Fifth Amendment due process clause, terminally ill patients should have early access to investigational therapies. This decision was later vacated and the case was sent back to the full court. In August 2007, the court found that terminally ill patients do not have a constitutional right to be treated with experimental drugs. An appeal to the U.S. Supreme Court was expected at the time the Council met to discuss this topic.

The Council strongly believed that the four phases of the drug approval process are designed to maximize drug effectiveness and safety and that the process should not be compromised by emotion. Statistically, only a small percentage of investigational
drugs for the treatment of cancer are ultimately approved for patient use; toxicity is a major reason why studies are stopped by the manufacturer or approval is denied by FDA. Lack of efficacy is also a concern during the early stages of clinical investigations. Although the Council had compassion for those individuals wishing to gain early access to therapies, the group supported FDA’s right to restrict access to protect the public health. Subsequent to the Council’s discussion, the Supreme Court declined to hear an appeal of the case.

**Appendix A—ASHP Statement on Criteria for an Intermediate Category of Drug Products**

**Position**

The American Society of Health-System Pharmacists (ASHP) supports the establishment of an intermediate category of drug products that would not require a prescription, but would be available from a pharmacist following appropriate patient assessment and professional consultation. These drug products would continue to be available by prescription from licensed health care professionals who are authorized to prescribe medications. Drug products appropriate for this intermediate category should have proven public health benefit and be identified by processes that include the input and advice of experts, such as pharmacists, physicians, and other licensed health care professionals. Identification of drug products for inclusion in the intermediate category should be based on the medical condition to be treated and potential adverse effects of the drug. Concerns that patients may not be able to fulfill a substantial self-care role associated with these drug products will be alleviated by taking into consideration the benefits of pharmacist oversight of these drug regimens. Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reporting should be collected and analyzed to evaluate the ongoing safety and effectiveness of drug products placed in this category. This information would be used to determine whether the product would remain in the intermediate category, return to prescription-only status, or move to nonprescription status.

**Background**

**Rationale for establishing an intermediate drug category.** Reclassification of prescription drug products to nonprescription status (e.g., antifungal vaginitis products and nonnarcotic antihistamines) has been associated with improvements in patient autonomy, health care knowledge, and self-care behavior. However, proposals to reclassify some prescription drug products to nonprescription status have been denied because of concerns about safety and whether patients would be capable of determining if they were suitable candidates for treatment. In 2008, for example, the Food and Drug Administration (FDA) ruled a third time against making lovastatin, an HMG-CoA reductase inhibitor (or statin), available without a prescription, although the predicted public health benefit of increasing availability of statins was estimated to range between 23,000 and 33,000 coronary heart disease events prevented per 1 million treated for 10 years. ASHP supports inclusion of statins in an intermediate category of drug products that provides the benefit of pharmacist oversight. Other drug products that should be considered for the intermediate category include injectable epinephrine to treat anaphylaxis; inhaled corticosteroids, leukotriene modifiers, and inhaled beta-2 agonists used in the treatment of asthma; select therapies for osteoporosis and hypertension; and vaccines. ASHP and other pharmacy organizations have long proposed the creation of an intermediate category of drug products that would bridge the large gap between prescription and nonprescription status. An intermediate drug category could improve patient access to medications that offer substantial public health benefit but present challenges for safety or effectiveness if used under existing models for nonprescription drug dispensing. Concerns with existing models include that products’ labeling information may be beyond the capacity of most consumers to understand (or may be subject to misinterpretation) or that monitoring procedures are not readily accessible to patients. Pharmacists’ expertise, licensure, and education—a six-year doctor of pharmacy degree that includes instruction on physiology, pharmacology, disease management, and physical assessment—make them well qualified to help patients make appropriate therapeutic decisions associated with use of these drug products.

The terms “behind-the-counter (BTC) drugs” and “pharmacist-only drugs” have also been used to describe the proposed intermediate category of drug products. While an FDA-established BTC category does not currently exist, the term BTC has been used to refer to drug products such as pseudoephedrine and levonorgestrel (marketed as Plan B) that are available for purchase only at the pharmacy counter. Implementation of that restriction has largely been a policing action (e.g., to restrict the amount of drug a patient can obtain or to confirm the patient’s age). In some instances, these functions are completed by pharmacy support staff under the supervision of a pharmacist. ASHP recommends use of the terminology intermediate category of drugs to describe drug products appropriate for this category that would be used by patients in conjunction with clinical assessment and consultation provided by pharmacists.

Distribution of the aforementioned nonprescription products via an intermediate-category model of dispensing could improve appropriate use of these products.

The purpose of this statement is to describe the criteria that should be used to identify drug products for inclusion in an intermediate category. While the practice implications of an intermediate drug category are briefly described, that discussion is beyond the scope of this statement. Pharmaco-economic analyses to assess the overall impact and costs of an intermediate category of drug products on patients, health systems, and health insurers should be conducted, and new models for reimbursement for pharmacists’ services should be developed. It should be noted that a small number of studies have demonstrated that overall costs to the health system decrease when the cost of these medications is not transferred solely to the patient. Alternative reimbursement models, such as insurance coverage for these products, would be necessary to optimize the use of the intermediate category of drug products.

**Criteria for an Intermediate Category of Drug Products**

Appropriate identification of drug products for inclusion in the intermediate category should address the concerns associated with a substantial self-care role for patients, by providing the benefits of pharmacist oversight of these drug therapy regimens (e.g., assessing for appropriate indications, contraindications, precautions, adverse drug events, drug interactions, and therapeutic response). ASHP believes drug products proposed for inclusion in the intermediate category should:

- Meet many of the criteria currently used to reclassify prescription drugs to nonprescription status (e.g., the drug product has a well-established benefit-to-risk ratio and a wide safety margin);
- Have been marketed as a prescription product for a length of time and used by a number of patients deemed sufficient by the FDA to detect serious adverse effects. Likewise, a product could be marketed as a nonprescription product, but would benefit from pharmacist oversight because safety and effectiveness concerns have arisen with its nonprescription use.

TPSs Currently Under Development. The Council reviewed and provided feedback on the following TPSs that are in various stages of development:

- **Treatment of Tuberculosis**
- **Safety and Efficacy of Propoxyphene in the Treatment of Mild to Moderate Pain**
- **Use of Corticosteroids for Pediatric Patients with Asthma**
Council on Therapeutics

- Have evidence of effectiveness and safety at the dose and regimen recommended for the formulation intended for intermediate classification; and
- Be used to prevent or treat a disease, symptom, or condition that can be readily detected by the patient or identified by the pharmacist or other health care provider.

Further, if the drug is used for a condition that requires laboratory or other medical monitoring, the pharmacy should be able to offer testing or have access to the results of that monitoring. Signs and symptoms of deterioration in health and the need for medical attention should be identifiable by the pharmacist or patient, as should signs demonstrating the effectiveness of the drug therapy. If the drug has the potential to rarely cause serious toxicity that can result in death or serious harm, there should be reliable early warning signs that can be readily detected and interpreted by the pharmacist or patient.

Anti-infective agents (systemic or other formulations) for which the emergence of resistance is a concern would not be appropriate for the intermediate category.

In applying these criteria, an independent decision should be made about each individual chemical entity, dosage form, and drug product, because differences among various members of a drug class and dosage forms prevent using therapeutic class as a basis for classifying groups of related drug products.

Because drug information is continually evolving, drug products in the intermediate category may be reclassified as prescription or nonprescription medications as new effectiveness and safety information becomes available. Similarly, products could be permanently classified in the intermediate category if ongoing evidence documents the necessity of pharmacist intervention to ensure safe and effective use. The postmarketing surveillance of these medications through cooperation of the FDA and product manufacturers should be supported, in part, by information reported by pharmacists and patients to an established surveillance system, such as MedWatch, or similar reporting mechanisms.

Practice Implications

Implementation of the intermediate drug category would require that an ongoing relationship be established and maintained between the pharmacist and the patient, and that documentation of the care provided be available to the patient's other health care providers, upon approval of the patient to provide such information. The exact nature and duration of the patient–pharmacist relationship would depend on the condition being treated and the drug therapy selected.

A practice model that includes collaboration among the patient, the pharmacist, and the patient's physician (or other primary care provider) would enhance use of these drug products and result in improved patient outcomes.

Increased pharmacist time for patient assessment, counseling, and documentation of services provided with these drug products will require reimbursement for these cognitive services. In addition, other conditions and procedures would be necessary to ensure the safety and effectiveness of these therapies, including the following:

- If the drug is to be used in conjunction with other therapies, such as diet and exercise, then information about those adjunct therapies should be readily available to the patient from the pharmacist, or through recommendation of the pharmacist or other health care provider.
- Pharmacist patient care services should be documented in the pharmacy record and available to be shared with other health care providers.
- Pharmacists and patients should provide information on actual or suspected side effects or drug interactions to programs, such as MedWatch, for the purposes of drug safety surveillance.
- Pharmacies should adopt standardized processes for the use of medications in the intermediate category that would guide patient triage, treatment, and referral to a physician when necessary. The expertise offered by clinical practice guidelines and professional associations should serve as the basis for these protocols, with appropriate modifications based on the unique characteristics of the patient population at the practice site.

- Pharmacies should adhere to quality measures that would be developed to assess the care provided (similar to those offered by the Pharmacy Quality Alliance) and engage in ongoing quality improvement activities to assess and improve the quality of services provided.

A detailed discussion of these topics is addressed by other ASHP position and guidance documents, including the ASHP Statement on the Pharmacist's Role in Primary Care; the ASHP Guidelines on Pharmacist- Conducted Patient Education and Counseling; the ASHP Guidelines on the Pharmacist's Role in the Development, Implementation, and Assessment of Clinical Pathways; the ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records; and the ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting.

Conclusion

An intermediate category of drug products would increase patient access to and benefit from drug products that otherwise would be available only by prescription. The use of appropriate criteria for classifying drug products in an intermediate drug category—in conjunction with pharmacist oversight of patient assessment, counseling, and monitoring—would improve public health without compromising patient safety.

References


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Reports on Sections and Forums

ASHP sections consist of members within five well-defined areas of health-system pharmacy who collaborate to advance professional practice in their respective areas. ASHP members may enroll in as many sections as they wish; practitioner members are asked to select one section as their primary "home," which allows them to vote for the chair and members of the executive committee of that section.

The ASHP Student Forum consists of all student members. The New Practitioners Forum consists of all practitioner members who are within five years of graduation from a college of pharmacy.

Each section and forum is led by an Executive Committee elected (sections) or appointed (forums) from the ASHP membership. Each Executive Committee met face to face June 22–23, 2007, to review the past year's activities and plan for the coming year. The committees met again on January 16, 2008, and by telephone periodically during the year to assess progress on initiatives and discuss new trends or events that warrant section or forum activity. Each section and forum has its own mission, vision, goals, and objectives.

1 ASHP Section of Clinical Specialists and Scientists
3 ASHP Section of Home, Ambulatory, and Chronic Care Practitioners
5 ASHP Section of Inpatient Care Practitioners
7 ASHP Section of Pharmacy Informatics and Technology
9 ASHP Section of Pharmacy Practice Managers
11 ASHP New Practitioners Forum
13 ASHP Pharmacy Student Forum
ASHP Section of Clinical Specialists and Scientists

The mission of the Section of Clinical Specialists and Scientists (SCSS) is to improve patient care by serving as a conduit for translating scientific advances in drug therapy and clinical therapeutics into the practice of pharmacy and advocating practice development and advancement. The SCSS Executive Committee has developed a strategic plan linked to the Section’s mission and goals. These goals are (1) effectively communicating the value members receive from their membership in the Section and ASHP; (2) enhancing efforts to encourage networking among Section members; (3) supporting the professional development of specialists and scientists; (4) promoting pharmacist implementation of evidence-based medicine; (5) facilitating the development of strategic internal and external partnerships; and (6) actively participating in ASHP’s policy and advocacy initiatives.

2007 Section Highlights. SCSS continues to grow significantly, with strong interest in the Section among students and new practitioners. Membership increased 4% during 2007 and now totals more than 11,000. Approximately 57% of the Section’s members have selected SCSS as their primary membership group.

Section members elected Kelly M. Smith as Chair and Erin Fox as a director-at-large; both will be installed at the June 2008 ASHP Summer Meeting.

SCSS selected Marianne Billeret, Pharm. D., BCPS, as the inaugural winner of the Clinical Specialists and Scientists Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of each section whose volunteer activities have supported the section’s mission and helped advance the profession. The award was presented at the 2007 Midyear Clinical Meeting (MCM).

Educational and Networking Opportunities. The Section’s Programming Committee is charged with developing programming at an advanced level that will be of interest to clinical specialists and scientists. The 2007-2008 committee developed more than 17 hours of educational programming on drugs with novel mechanisms of action and on significant advances in cardiology, infectious diseases, immunology, neurology, and critical care. In addition to developing two highly successful educational sessions (“In Case You Missed It: Top Papers in Medicine 2007” and “Significant Developments in the Medication Pipeline”), the committee planned a session devoted to debates in areas of therapeutic controversy and coordinated the Clinical Pearls session.

The Section’s electronic NewsLink is distributed biweekly to more than 12,000 ASHP members, providing news and current information on medical research, regulatory and health policy issues, health care, and therapeutics. The Section’s e-discussion group (EDG) provides a forum for Section members to exchange information and ideas on a wide variety of topics related to clinical practice; currently, more than 2000 members participate. The discussion group is also used to communicate urgent information on clinical specialty practice.

The Section has 17 specialty networks encompassing most areas of specialty pharmacy practice. The networks meet regularly at the MCM, with more than 1000 meeting attendees participating. Facilitators are appointed for each network by the Section’s Chair. The network facilitators monitor developments and trends in their therapeutic area and advise ASHP and the Section’s membership of these developments through the Section’s EDG, NewsLink, networking meetings, the Virtual Journal Club, and other avenues. The facilitators also serve ASHP and its members as therapeutic experts and contribute to ASHP advocacy and educational efforts.

Resources for Clinical Specialists and Scientists. The Section continues to enhance its resources for pharmacy practitioners in different specialty areas, and to use multiple communication pathways to notify Section members of new resources. The Section created a Virtual Journal Club on the website to enhance communication and participation among members with different specialties. This tool provides informal online discussion of advances in various therapeutic areas; the goal is to help pharmacists apply evidence-based medicine to practice. In addition, the Section created a new clinical column in the American Journal of Health-System Pharmacy (AHP) for discussion of cutting-edge issues. The column covers therapeutic controversies and provides recommendations for handling specific pharmacotherapeutic problems. The Section also developed an evidence-based practice resource center on the ASHP website. Its purpose is to familiarize pharmacists with the concept of evidence-based practice and help them learn to effectively utilize available resources. The Section has also created an advisory group on gene therapy to develop resources for practitioners.

Advisory Group on Emergency Care. In 2007 the Section’s advisory group on emergency care developed, and ASHP Board of Directors approved, 1 policy document (ASHP Statement on Pharmacy Services to the Emergency Department) addressing this growing practice area. Advisory group members also served as mentors for ASHP’s Emergency Department Patient Care Impact Program, a six-month experiential certificate program. In addition to numerous emergency-care-related programs at the 2007 MCM, a successful emergency medicine networking session at the meeting drew more than 150 participants. The advisory group also established an ASHP Emergency Care EDG for networking among practitioners in this setting.

Advisory Group on Investigational Pharmacy Services. The Executive Committee continues to recognize and support the needs of pharmacists working in the areas of investigational drugs and clinical research. The advisory group on investigational pharmacy services reviews current tools, identifies educational needs, and develops member resources. It is developing a survey to evaluate current investigational drug services in hospitals and health systems. The advisory group has also established an ASHP Investigational Drug Services EDG for networking among practitioners in this setting. For the 2008 MCM, the advisory group is planning an investigational drug services educational session, a “pearls” session, and a session on risk management.

Advocacy. The Section continues to support ASHP activities in collaborative drug therapy management, compensation for pharmaceutical care services, recognition of pharmacists as health care providers, residency and fellowship training, and credentialing for pharmacists. In each of these areas, the Section’s leadership provides input and recommendations to the Board of Directors and ASHP staff. The Section continues to work on the issues of clinical privileging and credentialing for pharmacists; currently available on the Section website are templates for establishing credentialing and privileging for clinical services in health systems and a companion document outlining a stepwise approach for implementing these processes.

The Section has been heavily involved in emphasizing the evidence-based nature of pharmacy practice and has worked to incorporate evidence-based medicine concepts into the ASHP Health-System Pharmacy 2015 initiative. The Section will continue to stress that the responsibility for incorporating evidence-based therapeutic guidelines and medication use into patient care is a responsibility of all pharmacists and pharmacy departments.
Specialty Practice and Credentialing. SCSS represents ASHP's continued commitment to meeting the needs of pharmacists in specialty practice settings and those working in the science of pharmacy practice. Members of the Section's Executive Committee believe that stakeholders from all of the pharmacy credentialing and certificate-granting programs should discuss an organized and rational model for pharmacist specialty practice. Discussions should address the utility of these credentials in privileging processes, and a plan should be developed for examining the processes for recertifying or maintaining specialty credentials to demonstrate continuing competence in the specialty. A white paper on pharmacist privileging in a health system was prepared by the Qualified Provider Model Ad Hoc Committee and published in AJHP (November 15, 2007). It described the rationale for and steps of pharmacist credentialing and privileging.

Conclusion. The Section offers members a sense of identity within ASHP and an organizational home dedicated to meeting their specialized practice, scientific, and research needs. The Section will continue to grow and expand its activities largely because of the efforts of its enthusiastic members and dedicated leaders.

Committee on Nominations
Ted L. Rice, Chair (Pennsylvania); Curtis D. Collins (Michigan); Rita K. Jew (California); Michael D. Katz (Arizona); Edward Li (Pennsylvania); Alan H. Mutnick (Ohio); Susan J. Skledar (Pennsylvania)

Programming Committee
Jean M. Schollitz, Chair (Pennsylvania); Kevin Garey, Vice-Chair (Texas); Curtis D. Collins (Michigan); Cherry W. Jackson (Alabama); Eric C. Kutscher (South Dakota); Karla Miller (Tennessee); Kevin G. Moores (Iowa); Melinda Neuhauser (Illinois); Mark A. Ninno (Florida); Lori Reinsner (California)

Advisory Group on Emergency Care
Daniel P. Hays, Chair (New York); Umbreen Murtaza, Vice-Chair (Maryland); Roshanak Aazami (California); Tony Casanova (Washington); Elizabeth A. Clements (Michigan); George Delgado (Michigan); Heather Draper (Tennessee); Frank P. Paloucek (Illinois); Renee M. Petzel (Illinois); Kevin O. Rynn (New Jersey); Joanne Witsil (Illinois); Marie Chisholm, Executive Committee Liaison (Arizona)

Advisory Group on Investigational Pharmacy Services
Bobby G. Bryant, Chair (Alabama); Joseph T. Dye (Georgia); Rita K. Jew (California); Darlette G. Luke (Minnesota); Tricia Meyer (Texas); Ronald Seto (Toronto, Canada); Kathleen Truelove (Maryland); Michael W. Kelly, Executive Committee Liaison (Iowa)

Network Facilitators
Anticoagulation: Snehal Bhatt (Massachusetts)
Cardiology: James C. Coon (Pennsylvania)
Critical Care: Lance J. Oyen (Minnesota)
Drug Information/Pharmacoeconomics: Mark A. Ninno (Florida)
Emergency Medicine: Daniel P. Hays (New York)
Geriatrics: Michelle Fritsch, (North Carolina)
Hematology/Oncology: Kamakshi Rao (North Carolina)
Immunology/Transplant: Nicole Weimert (South Carolina)
Infectious Diseases: Curtis Collins (Michigan)
Investigational Drugs/Critical Research: Bobby G. Bryant (Alabama)
Nutrition Support: Caitlin S. Curtiss (Wisconsin)
Pain Management: Christopher M. Herndon (Illinois)
Pediatrics/Obsterics–Gynecology/Neonatal: Anita Siu (New Jersey)
Pharmacokinetics: Rosa Yeh (Texas)
Primary Care/Pharmacotherapy: Alan J. Zillich (Indiana)
Psychopharmacy/Neurology: Sheila R. Botts (Kentucky)
Surgery/Operating Room/Anesthesiology: Eric L. Chernin (Florida)
ASHP Section of Home, Ambulatory, and Chronic Care Practitioners

Led by its Executive Committee, the Section of Home, Ambulatory, and Chronic Care Practitioners focused in 2007 on reimbursement for cognitive services, ambulatory care services, pain management and palliative care, and continuity of care. At the end of 2007 the Section had a total primary and secondary membership of 7332.

Section members elected Marc Stranz as Chair-elect, and he immediately began to serve in that capacity. Section members also elected Richard Stambaugh to a two-year term as director-at-large. The Committee on Nominations for 2008 will present a slate of candidates for one director-at-large position and for Chair-elect.

The Section selected Caryn M. Bing, M.S., FASHP, as the inaugural winner of the Home, Ambulatory, and Chronic Care Practitioners Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member from each Section whose volunteer activities have supported the Section’s mission and helped advance the profession. The award was presented at the 2007 Midyear Clinical Meeting (MCM).

Reimbursement for Cognitive Services. The Section Advisory Group on Reimbursement for Cognitive Services was formed to review current practices, give advice on educational needs, and develop member resources. The advisory group organized the Ambulatory Care Workshop at the 2007 MCM, which focused on documentation, collaborative drug therapy management agreements, medication therapy management opportunities, and rules for billing compliance. The workshop will be repeated in 2008. The advisory group also produced a webinar (Web-based seminar) networking session on reimbursement basics that was attended by more than 250 ASHP members at 160 locations. In addition, the advisory group published two articles in the American Journal of Health-System Pharmacy (AJHP) on reimbursement terminology and documentation skills and will submit a third article in 2008.

Pain Management and Palliative Care. The Section’s Executive Committee identified pain management and palliative care as areas in which students and new practitioners lack sufficient training, and in which ASHP could provide resources to support and improve practice. These areas include the management of acute and chronic pain and end-of-life care. A workshop provided by the Section’s Task Force on Pain Management and Palliative Care at the 2007 MCM was well attended and will be repeated in 2008.

The task force will be working with practitioners interested in creating a PGY2 specialty residency in pain management and palliative care. Initial discussions on the need for and general ASHP member interest in the proposed specialty residency took place at the 2007 MCM.

ASHP facilitated the inclusion of a Section member on the steering committee for the National Quality Forum’s Evidence-based Substance Abuse Treatment Practices, released in 2007.

Ambulatory Care Specialty Credential. The ASHP Board of Directors voted to initiate the process for establishing an ambulatory care specialty credential. ASHP, along with the American College of Clinical Pharmacy and the American Pharmacists Association, will be completing a petition for the proposed specialty credential as required by the Board of Pharmaceutical Specialties (BPS). The petition will use information from BPS’s Practice Analysis Task Force and from a survey of members of the three practitioner organizations.

Continuity of Care. Continuity of care continues to be a major emphasis of the Section. “Continuity of Care in Medication Management: Review of Issues and Considerations for Pharmacy” was published in AJHP in 2005, and the Section has used that document as a guide for strategic planning and education. ASHP and the ASHP Research and Education Foundation conducted a summit meeting in June 2007 using elements of that document and other Section resources. A summary of the meeting was published in AJHP (February 15, 2008). In addition, Section leaders participated in a medication reconciliation workshop that examined opportunities for ASHP and the American Pharmacists Association to consider in efforts to improve continuity of care.

Medication Reconciliation. In collaboration with the other ASHP pharmacy practice sections and the ASHP Pharmacy Standards and Quality Division, the Section has been active in developing education and tools for practitioners to support improvement in the medication reconciliation process. ASHP members, including members of the Section, participated in a Joint Commission medication reconciliation summit, providing input on potential changes in the national patient safety goal addressing reconciliation.

Practice Area Networks. The Section’s networks focus on the unique needs of Section members in various practice areas (i.e., home, ambulatory, and chronic care). The networks met at the 2007 MCM and addressed issues including reimbursement for cognitive services, the impact of new medication therapy management CPT codes, and USP Chapter 797.

Educational Programming. At the 2007 MCM the Section provided a Cutting Edge in Ambulatory Practice session and programming on aging in place and the challenges of managing chronic diseases. The programs were very well attended, and the Cutting Edge format will be repeated in 2008. The Section’s theme for the 2008 MCM will be “Chronic Disease: Adherence, Quality of Life, and Skills to Manage Patients.”

Advocacy. Many Section members represent ASHP on various coalitions and committees. The Section has provided member experts to the Pharmacy Quality Alliance, the National Quality Forum and its ambulatory care project and substance abuse treatment project, Joint Commission Professional and Technical Advisory Committees on ambulatory care and home care, and the National Asthma Education and Prevention Program. These members take the pharmacist’s perspective to discussions that have an impact on patient care nationwide. In cooperation with the American Society of Consultant Pharmacists, a webinar was conducted to provide information on Medicare Part D long-term-care rebates; feedback from members was communicated to the Centers for Medicare and Medicaid Services. Section members also provided information and support for ASHP’s advocacy efforts dealing with average sales price and National Drug Code outpatient reporting issues.

Conclusion. The Section of Home, Ambulatory, and Chronic Care Practitioners had a very productive year as it fulfilled members’ needs and continued striving to provide leadership and value for its members through its programs.

Executive Committee
Ernest Dole, Chair (New Mexico)
Marc Stranz, Chair-elect (Colorado)
Cathy L. Sasser, Immediate Past Chair (Georgia)
Timothy R. Brown (Ohio)
Barbara Petroff (Michigan)
Richard Stambaugh (Minnesota)
Sheila Mitchell, Board Liaison (Tennessee)
David F. Chen, Secretary
Committee on Nominations
Cathy L. Sasser, Chair (Georgia); Caryn M. Bing (Nevada); Sandra L. Chase (Michigan); Leona J. Dombroske (California); Mary Ann Kleethermes (Illinois); Carol J. Rollins (Arizona)

Programming Committee
Pamela L. Stamm, Chair (Alabama); Melissa Blair (North Carolina); Sandra L. Chase (Michigan); Michelle A. Fritsch (North Carolina); Katie V. Lai (Washington); Kimberly Braxton Lloyd (Alabama); Tracy A. Martinez (Michigan); Michele L. Matthews (Massachusetts); Edward P. Sheridan (Indiana); Anita Thomas (Indiana); Barbara J. Petroff, Executive Committee Liaison (Michigan)

Advisory Group on Reimbursement for Cognitive Services
Timothy R. Brown, Chair (Ohio); Kelly T. Epplen (Ohio); Roger S. Klotz (California); Sandra Leal (Arizona); Edith Nutescu (Illinois); Laura D. Roller (Utah); Amy Stump (Wyoming); Seena Zierler-Brown (Florida); Anne T. Jarrett, Liaison (North Carolina); David Chen, Staff Liaison

Task Force on Pain Management and Palliative Care
Douglas Nec, Co-Chair (California); Suzanne Nesbit, Co-Chair (Maryland); Sondra Adkinson (Florida); Thomas Bookwalter (California); Victoria Ferraresi (California); Christopher Herndon (Illinois); Kenneth C. Jackson (Oregon); Mary Lynn McPherson (Maryland); Lori Reisner (California); Jennifer Strickland (Florida); Cathy L. Sasser, Executive Committee Liaison (Georgia); David Chen, Staff Liaison
ASHP Section of Inpatient Care Practitioners

The Section of Inpatient Care Practitioners, led by its Executive Committee, works through educational programming, networking, advocacy, and volunteer opportunities to develop services that support the needs of the frontline pharmacist. The Section seeks to achieve a vision in which pharmacists practicing in an inpatient setting safely integrate clinical (direct patient care or indirect patient care), distributive, and operational functions and are focused on improving inpatient care. To achieve this vision, the Section's goals are to (1) serve as a voice for inpatient care practitioners and members of the Section within ASHP, including ASHP governance and integration of Section policy development within ASHP; (2) facilitate the integration of drug distribution and clinical practice for inpatient care practitioners and members of the Section, (3) promote the professional development of inpatient care practitioners and members of the Section through education and skills development, (4) increase communication with Section members on key issues for the profession and the Section, (5) encourage, facilitate, and educate on the application of ASHP best practices and evidence-based guidelines at the inpatient care practitioner level, and (6) identify and promote the development of leaders within the Section.

2007 Section Highlights. During 2007, the Section added more than 2100 members, for a total membership exceeding 9000. About 19% of the Section's members have selected it as their primary membership group. Section members elected Randy Kuiper as Chair and Jennifer Edwards as a director-at-large; they will be installed at the June 2008 ASHP Summer Meeting. The Section selected DeeAnn Wedemeyer-Oleson, Pharm.D., CGP, as the inaugural winner of the Inpatient Care Practitioners Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of each Section whose volunteer activities have supported the Section's mission and helped advance the profession. The award was presented at the 2007 Midyear Clinical Meeting (MCM).

Educational Programming. The Section planned and conducted successful educational programming at the 2007 MCM. For the second year, a one-day educational track for pharmacists working in small and rural hospitals was offered. Topics included medication safety, innovations in small and rural hospitals, and telepharmacy. Three highly attended networking sessions for these practitioners were also held, including sessions on remote order entry and high-alert drugs. Other programs developed to meet the needs of Section members focused on critical care, infectious diseases, and "Patient Safety Meets Just Culture." Networking sessions for medication safety officers, preceptors, and members interested in publishing were also offered. The Programming Committee met at the 2007 MCM to discuss topics and a potential theme for programming at the 2008 MCM.

Resources for Inpatient Care Practitioners. The Section's page on the ASHP website provides frontline pharmacists with information pertinent to their needs, including recent news, practical tools, and member spotlights. All members of the Section routinely receive an electronic NewsLink that provides information and notifies Section members of opportunities within the Section and ASHP. The Section's active e-discussion group (EDG) is an effective networking mechanism, enabling members to communicate rapidly on areas of interest and to receive vital information from various sources. The EDG for small and rural hospitals also continues to be very active.

A resource center for small and rural hospitals on the ASHP website enables members in these settings to share information, such as pharmacist position descriptions. The Section also plans to continue holding Web-based seminars (webinars) for its members.

In addition to the activities of the Section's three advisory groups, described below, the Section's Task Force on Pharmacy Practice Experiences provides tools and resources for preceptors and potential preceptors, including a toolkit to help preceptors with student rotations.

Advisory Group on Small and Rural Hospitals. The Section Advisory Group (SAG) on Small and Rural Hospitals (SHR) maintains an active EDG. The group planned a successful all-day educational track and three networking sessions at the 2007 MCM. It plans to provide input on proposed ASHP policies dealing with issues in small and rural hospitals. The group maintains a close working relationship with the National Rural Health Association (NRHA) and is involved in planning for the inaugural National Rural Pharmacy meeting, hosted by the University of Minnesota and NRHA.

Advisory Group on Publications. The SAG on Publications has contributed several articles to the Frontline Pharmacist column in the American Journal of Health-System Pharmacy. It conducted a successful networking session at the MCM for members interested in publishing their first article.

Advisory Group on Medication Safety. The SAG on Medication Safety is charged with providing tools and resources for medication safety officers or pharmacists who have medication safety responsibility as a component of their position. The group plans to publish a primer on medication safety, and it has contributed to the ASHP Patient Safety website. The group conducted three successful networking sessions at the 2007 MCM, including a session on medication reconciliation.

Advocacy. The Section's Executive Committee has suggested that ASHP seek ways to work with external organizations dealing with small and rural hospitals. The Office of Rural Health Policy and NRHA are two such organizations with which ASHP has strengthened ties. ASHP staff recently presented information on the value of pharmacists at NRHA's annual critical access hospital meeting.

Conclusion. The Section of Inpatient Care Practitioners continues to grow and serve its members. Through the work of its volunteer members, the Section has been successful in developing programs, tools, and resources that help meet the needs of the frontline pharmacist.

Committee on Nominations
Megan K. McMurray, Chair (Illinois); Dale E. English II, Vice-Chair (Ohio); Ronald Barnes (Georgia); Tammy Cohen (Texas); Deb Saine (Virginia)

Programming Committee
Laura C. Wachtler, Chair (Maryland); Paul D. Mangino, Immediate Past Chair (Kentucky); Catherine Christen (Michigan); Rick Knudson (Iowa); Joanne Kowiatek (Pennsylvania); Lois Parker (Massachusetts); Susan Jean Skledar (Pennsylvania); Linda Spooner (Massachusetts); Trish Wegner (Illinois); Debra L. Cowan, SRH SAG Liaison (North Carolina); Matthew P. Fricke, SRH SAG Liaison Alternate (Pennsylvania); Brian Benson, Executive Committee Liaison (Iowa); Michelle Abalos, Staff (Maryland)
Advisory Group on Publications
Tammy Cohen, Chair (Texas); Catherine Christen (Michigan); Sandra C. Hennessy (Massachusetts); Bonnie A. Labdi (Texas); Matthew Levanda (New Jersey); Jacqueline L. Olin (New Jersey); Susan Jean Skledar (Pennsylvania); Jennifer Edwards, Executive Committee Liaison (Montana); Sharon Park, Staff (Maryland)

Advisory Group on Small and Rural Hospitals
Timothy P. Stratton, Chair (Minnesota); DeeAnn W. Oleson, Immediate Past Chair (Iowa); Debby Lynn Painter Cowan (North Carolina); Paul Driver (Idaho); Matthew Fricker (Pennsylvania); Dallas Moore (Utah); Bruce Thompson (Minnesota); Allen J. Vaida (Pennsylvania); Paul D. Moore, NRHA Liaison (Oklahoma); Helen Calmes, Executive Committee Liaison (Louisiana); Randy Kuiper, Executive Committee Liaison (Montana)

Advisory Group on Medication Safety
Deb Saine, Chair (Virginia); Paul F. Davern (Connecticut); Lynn Eschenbacher (North Carolina); Rachel R. Forster (Nebraska); Nancy Granger (Tennessee); Nicole L. Molienkopf (Maryland); Linda S. Tyler (Utah); Patricia R. Knowles, Executive Committee Liaison (Georgia); Brian D. Benson, Executive Committee Liaison (Iowa); Bona E. Benjamin, Staff (Maryland)

Task Force on Pharmacy Practice Experiences
Debbie Sisson, Chair (Minnesota); Beth D. Ferguson (Minnesota); T. Kristopher Harrell (Mississippi); Gerald Meyer (Pennsylvania); Dale E. English, Executive Committee Liaison (Ohio); Jennifer M. Edwards, Executive Committee Liaison (Montana)
ASHP Section of Pharmacy Informatics and Technology

The Section of Pharmacy Informatics and Technology was formed in November 2006 to identify and address the unique needs of pharmacy departments and the personnel associated with pharmacy activities related to informatics, technology, and automation. A Section Executive Committee was elected in 2007. The Executive Committee has developed a strategic plan linked to the Section’s mission and goals. The goals are to (1) demonstrate and communicate the value of belonging to the Section, (2) advocate the development of strategic internal and external partnerships, (3) promote implementation of evidence-based medicine and development of best practice standards for informatics and technology, (4) foster education, training, and development opportunities for Section members, (5) expand awareness of the importance of pharmacy informatics in health systems, and (6) promote opportunities for research in pharmacy informatics.

2007 Section Highlights. During 2007, the Section added more than 2100 members. About 26% of the Section’s members have selected it as their primary membership group. Section members elected Mark Siska as Chair and Dennis Tribble as Chair-elect. Jeff Ramirez and John Polkoonen were elected as directors-at-large. Brent Fox was elected to serve as a director-at-large in 2008 to 2010. Tribble and Fox will be installed at the June 2008 ASHP Summer Meeting. The Section selected Toby Clark, M.S., FASHP, as the inaugural winner of the Pharmacy Informatics and Technology Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of each Section whose volunteer activities have supported the Section’s mission and helped advance the profession. The award was presented at the 2007 Midyear Clinical Meeting (MCM).

Educational Programming. Five sessions for pharmacists interested in informatics were presented at the 2007 MCM. The topics included e-prescribing, medication distribution systems (cart-fill versus non-cart-fill), key issues in informatics, knowledge management for pharmacists, and implementation of technology in specialized settings. The Programming Committee coordinated the Informatics Bytes “pearls” session. John Polkoonen was Chair of the Section’s 2006–2007 Programming Committee.

The Section also planned and implemented four networking sessions on the topics of bar coding, computerized provider order entry (CPOE), pharmacy informatics residencies, and preliminary results of the Section’s survey on information technology and automation.

The Section will provide more than 14 hours of continuing-education programming for the 2008 MCM. The topics will include e-prescribing, medication distribution systems, bar-code medication administration, clinical decision support, experiences with technology in Veterans Affairs facilities, and use of technology to detect controlled substance diversion. The Section is working with the Section of Pharmacy Practice Managers to develop a joint session on emerging technologies. The Programming Committee will again coordinate the Informatics Bytes session.

Electronic Networking Opportunities. The Section’s electronic NewsLink is distributed monthly to more than 2700 ASHP members. The NewsLink covers current issues relating to informatics and technology, research, legislative and regulatory facts, and health policy and health care news. The Section’s e-discussion group (EDG), which includes 1900 participants, provides a forum for Section members to exchange information and ideas on a wide variety of topics related to pharmacy informatics and technology. The EDG list is also used to communicate urgent information from the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration, and the Joint Commission that may have an impact on the Section’s membership.

Section Advisory Groups and Task Forces. Through an assessment of the needs of Section members, the Executive Committee and staff identified four areas in which more information would be useful to Section members. Section advisory groups and task forces based in those areas were created; each was charged with developing two or more projects that support members in their day-to-day practice.

The Advisory Group on Clinical Information Systems is focusing on the following topics: the development of CPOE guidelines, prescribing (e-prescribing) recommendations, electronic medication reconciliation processes, and clinical decision support systems. The CPOE guidelines are being revised by the advisory group and should be available for comment by April 2008. The group will be developing guidance for e-prescribing of controlled substances.

The Advisory Group on Automation and Documentation is involved in the following activities: management of the medication supply-chain process, preparation of medications and dispensing of medications with robotics, medication administration with bar-code medication technologies and smart pumps, and clinical documentation. The Executive Committee suggested that the advisory group develop resources for the implementation of automation architecture in a multiple-site health system. The advisory group actively supports initiatives related to bar-code medication administration. The group developed the ASHP Statement on Bar-Code-Enabled Point-of-Care Technology, which is being submitted to the ASHP House of Delegates for approval in June 2008.

The Task Force on Education and Publications is supporting the Section by updating and maintaining the Section’s website and resource centers; supporting the development of informatics residency programs and other educational opportunities for pharmacists, students, technicians, and vendors; and establishing a column in the American Journal of Health-System Pharmacy (AJHP). The Informatics Interchange column is scheduled to debut in the June 1, 2008, issue.

The Task Force on Standards and Regulations is establishing a process for developing comments on upcoming government regulations and standards issued by other groups. The purpose is to provide examples of best practices for meeting regulations and standards and to work with organizations such as ASTM, HL-7, and ANSI to develop standards that affect the medication-use process. The task force provided comments to the Certification Commission for Healthcare Information Technology on its draft criteria for inpatient electronic health records in December 2007. The Task Force also submitted comments on e-prescribing to CMS.

ASHP Survey of Pharmacy Informatics, Technology, and Automation in Health Systems. Findings of an ASHP national survey on information technology, which was funded by a grant from McKesson, Inc., were discussed at the 2007 MCM. By December 26, 2007, when the survey ended, more than 1000 directors of pharmacy had completed it. The data were made available for the Health Information Management Systems Society annual meeting in February 2008, and the complete findings will be published in AJHP.

Conclusion. The ASHP Section of Pharmacy Informatics and Technology is dedicated to improving health outcomes through the use and integration of data, information, knowledge, technology, and automation in the medication-use process. The Section is excited about carrying its mission forward in an area that is quickly changing the face of health care.
Committee on Nominations
Kevin C. Marvin, Chair (Vermont); Scott R. McCreadie, (Michigan); Mark H. Siska (Minnesota)

Programming Committee
Michael D. Schlesselman, Chair (Connecticut); Alan Chung (Tennessee); Robert Christiansen (Pennsylvania); Elizabeth Fields (Tennessee); Maritza Lew (California); John Manzo (New York); Dallas Moore (Utah); Ian Orensky (Virginia); Lynn C. Sanders (District of Columbia); Lolita White (Maryland); Mark H. Siska, Executive Committee Liaison

Advisory Group on Clinical Information Systems
Bonnie Levin, Chair (District of Columbia); J. Chad Hardy, Vice-Chair (Texas); Matt Baila (Indiana); Anne Bobb (Illinois); Denny C. Briley (Illinois); Charles R. Downs (Maryland); Francis J. Dunn, Jr. (New Hampshire); Edwin Eason (Texas); Randy Herring (Alabama); John R. Horn (Washington); Timothy R. Lanese (Ohio); Tommy Mannino (Louisiana); Cathy Meives (Missouri); Donald R. O'Brien (Wisconsin); Kellie Stachura (Maryland); David L. Troiano (Texas); Lori Wright (Tennessee); Jennifer Boehne, Student Member; Denis J. (Jeff) Ramirez, Executive Committee Liaison

Advisory Group on Automation and Documentation
Christopher J. Urbanski, Chair (Indiana); Arash T. Dabestani, Vice-Chair (Virginia); James Besier (Ohio); Leslie Brookins (Missouri); Ron Burnette (Florida); Kimberly Dove (California); Candace J. Fong (California); Craig P. Frost (Texas); Rick K. Glabach (Maryland); Gary L. Johnson, Jr. (Washington); Kim William Morimoto (California); Brad Rognrud (Minnesota); Paul M. Seelinger (California); Charlie De la Torre (Florida); Gwen Volpe (Illinois); Jennifer Mullen, New Practitioner Member; Ericka A. Curry, Pharmacy Technician Member; Dennis A. Tribble, Executive Committee Liaison

Task Force on Education and Publications
Terry Seaton, Chair (Missouri); Ross Edward Vanderbush, Vice-Chair (Arkansas); David Angaran (Florida); Lou Barone (Ohio); Kevin Clauson (Florida); Carol Hoje (Utah); Douglas B. Kent (Pennsylvania); John C. Poikonen (Massachusetts); Marc Young (Maryland); Mai-Chi Tran, Student Member; Brent Fox, Executive Committee Liaison

Task Force on Standards and Regulations
Michael McGregory, Chair (Michigan); Kevin C. Marvin, Vice-Chair (Vermont); Michael A. Jones (Colorado); Ed Millikan (Maryland); Sandra H. Mitchell (Maryland); Alan M. Portney (Pennsylvania); Scott M Robertson (California); Suzanne B. Shea (Texas); John C. Poikonen, Executive Committee Liaison
ASHP Section of Pharmacy Practice Managers

The mission of the Section of Pharmacy Practice Managers (SPPM) is to help members manage pharmacy resources, maximize the utility of medication-use systems, develop future leaders, and promote the pharmacist’s role in patient care. The SPPM Executive Committee has developed a strategic plan linked to the mission and goals of the Section. These goals are (1) maximizing communications and interactions with and among Section members, (2) fostering education, training, and development opportunities for managers and leaders, (3) recommending professional policy and advocacy on issues of importance to Section members, (4) supporting members in developing and managing staff and in the advancement of pharmacy practice, and (5) helping members improve adherence to ASHP practice standards and other best practices.

2007 Section Highlights. The Section added more than 1000 new members in 2007, a 13% increase from the previous year. Approximately 45% of the Section’s members have selected SPPM as their primary membership group. Section members elected James Rinehart as Chair and Paul Mosko as a director-at-large; both will be installed at the June 2008 ASHP Summer Meeting. SPPM recognized Rita Shane as the inaugural winner of the Pharmacy Practice Managers Distinguished Service Award. Established in 2007, the ASHP Pharmacy Practice Sections Distinguished Service Award recognizes a member of each section whose volunteer activities have supported the section’s mission and helped advance the profession. The award was presented at the 2007 Midyear Clinical Meeting (MCM).

Conference for Leaders in Health-System Pharmacy. The Section, in collaboration with ASHP Advantage, planned and implemented another successful leadership conference. This event, which attracted approximately 400 participants, included key programs in areas such as bar-code technology, informatics infrastructure and patient safety, and medication reconciliation. Additional highlights were the inaugural “new managers’ boot camp” and presentation of the John W. Webb Lecture Award to Marianne F. Ivey.

Educational and Networking Opportunities. Under the leadership of Todd Karpinski, the 2006–2007 Programming Committee designed four educational sessions for pharmacy managers and directors that were presented at the 2007 MCM. The topics included recruitment and retention, emerging trends in health-system pharmacy, using pharmacy metrics in departmental strategic planning, and management “pears.” All of these sessions were recorded and synchronized with the presentation slides so that they can be made available to members on the SPPM website. For the 2008 MCM, the committee is planning sessions on fundamental skills for new managers, gaining value from innovations in information technology, and technology safety. The Section also planned and implemented five networking sessions at the 2007 MCM, on financial management and reimbursement, new managers, the 340B program, multihospital systems, and workload and productivity monitoring.

The Section continues to distribute a monthly electronic NewsLink that serves over 8000 ASHP members. The NewsLink provides management paradigms, business information, relevant reports, legislative updates, regulatory alerts, and health policy/health care news. The Section also continues to facilitate an e-discussion group (EDG) with approximately 1500 participants. The EDG provides a forum for Section members to exchange information and ideas on a wide variety of topics related to pharmacy management and leadership. The EDG list is also used to communicate urgent information from the Centers for Medicare and Medicaid Services, the Food and Drug Administration, and the Joint Commission.

Advisory Group on Financial Management and Reimbursement. The accomplishments of the Section Advisory Group on Financial Management and Reimbursement include facilitating a networking session during the 2007 MCM, developing and posting on the SPPM website an article on managing the pharmacy chargemaster, and creating and posting on the SPPM website a reimbursement fundamentals teaching tool entitled “The Reluctant Pharmacist.” The group also assembled and posted on the SPPM website a revenue optimization checklist with key strategies for increasing and maximizing revenue in pharmacy departments. In addition, the group disseminated results from a financial management survey that yielded information on cost-reduction strategies and other items. The group also contributed to the new managers’ boot camp sessions at the 2007 Conference for Leaders in Health-System Pharmacy and participated in the 2007 MCM Management Pearls session.

Advisory Group on Leadership Development. Activities of the Section Advisory Group on Leadership Development included a survey to gather data on management and leadership opportunities for students and residents and the development of a standardized presentation on leadership opportunities for use with pharmacy students at affiliated state society meetings. The group also collected a wide spectrum of materials, including the survey results, to be included in an Online Pharmacy Leadership Resource Center. The group is exploring ways to continue collaboration with the Center for Health-System Pharmacy Leadership to promote leadership development for clinicians.

Advisory Group on Manager Development. The Section Advisory Group on Manager Development is designing resources and implementing initiatives to promote the positive attributes of pharmacy leadership positions. In addition, a toolkit to assist managers in their daily operations is being developed. The group is also assembling a list of management development programs that are offered throughout the nation. to be posted on the SPPM website.

Advisory Group on Workload and Productivity Monitoring. The Section Advisory Group on Workload and Productivity Monitoring has completed and developed plans for promoting a workload and productivity benchmarking primer. The group introduced in the 2007 House of Delegates a resolution regarding financial outcomes achieved through pharmacists’ participation in patient care. Future initiatives include developing tools, materials, and programs to assist members in achieving the ASHP workforce vision and helping managers advocate the advancement of pharmacy services.

Advisory Group on Publications. The Section Advisory Group on Publications has reviewed and approved three articles that are slated for publication in the Management Consultation column of the American Journal of Health-System Pharmacy. The topics are the director of pharmacy services position, managing the chargemaster, and aptitude for a management position in health-system pharmacy practice. The group has expanded its mission and purpose; in addition to working to increase the volume and applicability of publications that enhance and promote administrative pharmacy, the group will also collaborate with all SPPM advisory groups to promote and disseminate the work of the Section.

Conclusion. The ASHP Section of Pharmacy Practice Managers represents ASHP’s continued commitment to meeting the needs of pharmacists who lead and manage departments of pharmacy. The Section provides pharmacy directors and managers with a sense of identity within ASHP and an organizational home dedicated to meeting their special needs.
Committee on Nominations
Andrew Wilson, Chair (Virginia); Paul Bush, (South Carolina); David Kvacncz (Ohio); Scott Mark (Pennsylvania); Donna Soffin (Nebraska);
Edward Stemley, Secretary

Programming Committee
Lance Swearingen, Chair (Minnesota); Rafael Saenz, Vice-Chair (Pennsylvania); Lynn Beichler (Oregon); Michael Benedict (Colorado);
John Clark (Michigan); Stephen Ecket (North Carolina); Ryan Forney (Ohio); Staci Hermann (Wisconsin); Thomas Kirschling (Pennsylvania);
Audrey Nakamura (California); Michael Nnadi (North Carolina); John Pastor (Minnesota); Scott Knoer, Executive Committee Liaison (Minnesota)

Advisory Group on Financial Management/Reimbursement
Anne Jarrett, Chair (North Carolina); Shabir Somani, Vice-Chair (Washington); Rita Shane, Immediate Past Chair (California); Tammy Cohen (Texas); Philip Johnson (Florida); Karl Kappeler (Ohio); Laura Mark (Pennsylvania); Nancy Nguyen (California); Fred Payne (North Carolina); Gregory Polk (Michigan); Jack Temple (North Carolina);
Kathleen Pawlicki, Executive Committee Liaison (Michigan)

Advisory Group on Leadership Development
Christopher Fortier, Chair (South Carolina); Tad Gomez, Vice-Chair (Georgia); Niesha Griffith, Immediate Past Chair (Ohio); Phil Brummond (Minnesota); Jennifer Cimoch (New Jersey); Cyndy Clegg (Washington); Brian Cohen (Texas); Lisa Gersema (Minnesota); Douglas Miller (Georgia); Coralynn Trewet (Iowa);
Jennifer Tryon (Oregon); Samaneh Wilkinson (Kansas); Karol Wollenburg (New York); Carol Woodward (West Virginia); Steve Rough, Executive Committee Liaison (Wisconsin)

Advisory Group on Manager Development
Todd Karpinski, Chair (Illinois); Wayne Boheneck, Vice-Chair (Ohio); John Clark (Florida); Amanda Hafford (Ohio); Nathan Hanson (Kansas);
Christene Jolowsky (Minnesota); Linzay Kelly (Texas); Rosario Lazzaro (New Jersey); Fred Massoomi (Nebraska); Robert Miller (California); Stephanie Feshek (Ohio); Ross Thompson (Massachusetts); Scott Knoer, Executive Committee Liaison (Minnesota)

Advisory Group on Workload and Productivity Monitoring
Michael McDaniel, Chair (Alabama); Heather Koko, Vice-Chair (South Carolina); James Rinehart, Immediate Past Chair (Nebraska);
Adam Bauman (Ohio); Michael Brownlee (Oregon); Dave Ehler (Minnesota); Howard Glazier (California); Paul Krogh (Minnesota);
Shane Madsen (Minnesota); Kathleen Moorman (Florida); Karen Nordstrom (Illinois); Chad Stashek (Wisconsin); John Worden (Kansas);
James Rinehart (Nebraska), Executive Committee Liaison

Advisory Group on Publications
Scott Mark, Chair (Pennsylvania); Michael Sanborn, Vice-Chair (Texas); Rick Couldry (Kansass); Erin Hendrick (Colorado); Michael McGregory (Michigan); Sylvia "Homley (Wisconsin); Michael Todaro (Mississippi); Paul Mosko, Executive Committee Liaison (Ohio)
ASHP New Practitioners Forum

The New Practitioners Forum is led by a five-member Executive Committee appointed each year by the ASHP President-elect and approved by the Board of Directors. The Executive Committee is responsible for advising the Board and ASHP staff on the overall direction of the Forum, including membership services, programs, and resources. The Executive Committee Chair is an invited participant in the strategic-planning meetings of the Board and serves as a voting new practitioner member of the ASHP House of Delegates. Each Executive Committee member heads one of the Forum’s five advisory groups.

Strategic Goals and Objectives. The Executive Committee established five strategic goals, with accompanying objectives, to direct the Forum’s operations:

1. Serve the unique educational and informational needs of new practitioner members. Objectives: (1) Conduct continual assessment and analysis of evolving professional needs and the effectiveness of Forum programs to meet these needs. (2) Provide programs and publications that meet the educational and informational needs of Forum members. (3) Enhance awareness of the Forum’s educational resources available to new practitioners and graduating students. (4) Promote utilization of section programs and services as related to new practitioners’ practice needs. (5) Foster increased communication among Forum members and other members of ASHP.

2. Cultivate professionalism in new practitioners. Objectives: (1) Expand collaboration between Forum members and others in ASHP, including section and Student Forum members. (2) Provide career development tools for new practitioners. (3) Promote new practitioner participation and recognition within the Forum and ASHP. (4) Encourage new practitioner involvement on the state affiliate level.

3. Foster leadership skills in members of the New Practitioners Forum. Objectives: (1) Promote leadership opportunities for New Practitioners Forum members within the Forum and ASHP. (2) Provide programs and resources that promote leadership skill development.

4. Promote membership and active involvement in the ASHP New Practitioners Forum. Objectives: (1) Actively recruit new members and encourage renewal to existing members of the Forum. (2) Enhance visibility and create greater awareness of the Forum through promotion of its initiatives and the accomplishments of its members. (3) Apply a variety of communication mechanisms to enhance overall promotion of benefits and services available to Forum members. (4) Promote active involvement of new practitioner members in the Forum and ASHP.

5. Cultivate awareness and engagement of new practitioners in practice advancement initiatives. Objectives: (1) Create awareness of the role new practitioners can have in legislative and professional policy advocacy. (2) Promote involvement in public relations initiatives. (3) Foster awareness and engagement in professional teamwork and collaborative approaches to practice.

Landmark achievements consistent with these goals and objectives in 2007–2008 included hosting the second Great eXpectations conference for new practitioners, launching a redesigned Mentor Exchange on the ASHP website, producing a contemporary video highlighting Forum membership benefits and opportunities for involvement in ASHP at many levels, launching the New Practitioners Forum Distinguished Service award, and developing a “webinar” series geared to the unique career development needs of new practitioners. The Forum was also successful in securing funding for the third Great Expectations conference to be held this fall.

Advisory Groups. The Chair of the New Practitioners Forum Executive Committee appoints Forum members to advisory groups in June, placing 60 new practitioners in leadership positions. The advisory groups are charged with providing feedback, guidance, and assistance in achieving the Forum’s strategic goals. This year, the Executive Committee eliminated the Education advisory group and created two new advisory groups focused on specific educational needs: Professional Practice and Science and Research.

Executive Committee
Sarah E. Ferrell, Chair (Kaiaias)
Lindsey R. Kelley, Vice-Chair (Minnesota)
Jeffrey S. Gildow (Nebraska)
Joshua E. Howell (Maryland)
Daryl S. Schiller (New York)
Kathryn R. Schulz, Board Liaison
Jill L. Haug, ASHP Staff Secretary

- The Membership and Outreach Advisory Group is charged with advancing the objectives set forth in strategic goal 4. This year the group has concentrated on increasing personal outreach to improve membership renewal and retention and on increasing the awareness of membership benefits that can assist new practitioners with their career development and daily practice needs.
- The Communications and Public Affairs Advisory Group is charged with advancing the objectives set forth in goal 5. Priorities this year include contributing articles to the American Journal of Health-System Pharmacy (AJHP), increasing involvement in ASHP grassroots advocacy efforts through collaboration with the ASHP Government Affairs Division, and working with the ASHP Public Relations Division to promote ASHP initiatives.
- The Leadership and Career Development Advisory Group is charged with advancing the objectives set forth in goals 2 and 3. Its priorities in the past year included identification of topics addressing career development for the New Practitioners Forum column in AJHP, Forum webinar series, and meeting programming. The advisory group continues to explore collaborative opportunities with the ASHP Research and Education Foundation’s Center for Health-System Pharmacy Leadership and is represented by two individuals on the Center’s Student/New Practitioner Task Force.
- The Professional Practice Advisory Group is charged with advancing the objectives set forth in goal 1, specific to professional practice issues. Its priorities this year have been contributing to the New Practitioners Forum column in AJHP, identifying Web content pertinent to new practitioners’ practice needs, and highlighting new practitioners who have demonstrated practice success.
- The Science and Research Advisory Group is charged with advancing the objectives set forth in goal 1, specific to science and research issues. Priorities this year include identifying science and research topics for website enhancement and the Forum webinar series. The advisory group is exploring opportunities to collaborate with the ASHP Research and Education Foundation.

Meetings and Programming. The second conference specifically for new practitioners, Great eXpectations, was held September 14–16, 2007, in Chicago and was enormously successful. High-tech, interactive, fresh, and fun, the conference allowed new practitioners to learn, network, and move forward in their careers. It offered skill-building sessions in four learning tracks: Developing Your Clinical Skills, Unique Roles and Career Paths for New Practitioners, Surviving Your Workplace, and Personal Career Development. Attendees also had many opportunities to mix and mingle with fellow new practitioners from across the country.

The 2007 Midyear Clinical Meeting (MCM) offered a variety of programs and opportunities for new practitioners. New practitioners participated in the residency showcase and personnel placement service. For the second consecutive year, a one-day educational track for new practitioners was offered. The highly attended sessions, planned in cooperation with the Forum, included Practical Evidence-Based Medicine for the Clinician, Optimizing Pharmacotherapy during Advanced Cardiac Life Support, and Preparing for Certification: Tales from the Frontlines. A reception just for new practitioners was held immediately following the programming. A networking room for new practitioners was available throughout the meeting, giving them a place to meet with peers in an informal setting. The Forum’s Executive Committee and advisory group members hosted a “meet and greet” session in the networking room, enabling members to talk with these leaders about opportunities for involvement in the Forum. Executive Committee members also represented the Forum in the ASHP Membership booth and lounge.
The Forum will launch a webinar (Web-based seminar) series in April, focusing on the unique career development needs of new practitioners as they graduate and develop throughout their first five years of practice. The inaugural webinar will pair a familiar pharmacy leader, Sara White, with two new practitioners and will focus on leading without a formal title and in an environment where one might be younger or less experienced. The Forum recognizes that practitioners early in their careers cannot always attend national meetings, and these webinar programs will allow new practitioner members to take advantage of ASHP educational programs from a distance.

Communications. The Forum’s own EDG, launched in April 2007, has been popular. New practitioners post inquiries and responses on clinical practice issues and career development topics. In addition, twice a month all members of the Forum receive a NewsLink for New Practitioners, which provides information relevant to recent graduates, communicates deadlines, and helps recruit members for greater involvement in the Forum. The NewsLink has enabled the Forum to recruit new practitioner authors, advisory group members, and volunteers for various outreach efforts and to identify new practitioners to highlight on the Web.

The Forum has its own area on the ASHP website, where new practitioners can find information pertinent to their needs, such as updates on Forum activities, career development resources, leadership opportunities, and a personal message from the Forum Executive Committee. Efforts have focused on making the site a clearinghouse for career development, clinical, precepting, and administrative and management resources to meet new practitioners’ varying informational needs. This section of the website also highlights each member of the Executive Committee and allows Forum members to communicate directly with these leaders.

New Practitioners Forum Column. Members of the Forum are contributing authors for the ASHP New Practitioners’ Forum column. The topics, pertinent to the needs of practitioners just starting their careers, have included a residency and a legislative article series. The column offers new graduates the chance to learn about writing for a professional journal and increases their awareness of opportunities for new practitioners in ASHP.

College of Pharmacy Outreach. Forum members desire to mentor students and share experiences with peers. To this end, members of the Forum Executive Committee visited colleges of pharmacy throughout the year to promote ASHP membership, provide information on pursuing residencies, promote the value of involvement in professional organizations, and explain how to become more engaged in professional endeavors on the local, state, and national level.

Volunteers represented the Forum at each of the five regional residency conferences during the spring. This was an opportunity to promote the Forum and encourage peers to become involved in the many opportunities ASHP offers exclusively for new practitioners.

Section Collaboration. Forum members share common professional and career development needs, but their varied practice needs are addressed through involvement in the ASHP pharmacy practice sections. Many new practitioners hold positions on section committees and advisory groups.

Mentor Exchange. The program previously known as the ASHP Virtual Mentoring Exchange was redesigned in October 2007 and relaunched by the New Practitioners Forum as the ASHP Mentor Exchange. It provides the opportunity for new practitioners to seek guidance and professional development advice from more experienced practitioners. Use of this members-only benefit from ASHP continues to grow, with several hundred mentors and mentees participating.

Membership Video. The Forum has created a video highlighting Forum membership benefits and promoting ways to get involved in ASHP on a variety of levels. Taping occurred at the Great expectations conference and the MCM and at ASHP headquarters during a Resident Visit program. The video will be an integral part of the Forum’s outreach to peers.

ASHP Resident Visit Program. For many years ASHP has invited residents in accredited programs to visit ASHP headquarters. These all-day visits give residents an inside glimpse of ASHP operations and an opportunity to learn about the many ways to get involved in ASHP and the resources available to them as new practitioner members. Four visits are held each year, two in the fall and two in the spring, with more than 100 residents participating. ASHP has redesigned the program in recent years. Now, participants not only learn but actively participate and provide feedback to ASHP on issues of importance.

Conclusion. The New Practitioners Forum continues to rapidly expand its programs and leadership opportunities. The continuation of the Great expectations Conference, the ASHP Resident Visit program, and the new practitioner educational track at the MCM demonstrate the commitment of ASHP and the Forum to meeting the unique needs of new practitioner members. The continual creation and provision of career development tools, leadership opportunities, and other resources and movements for opportunities for collaboration with the ASHP practice sections also show support for this membership group. By meeting their needs, ASHP hopes to foster professional development in new practitioners that extends into greater involvement in ASHP and state and local health-system pharmacy organizations.

Advisory Group on Membership and Outreach
Sarah Ferrell (Kansas), Benjamin Anderson (Pennsylvania), Laura Butkiewich (Missouri), Ashley Dalton (California), Lauren Decloe (Maryland), Pranish Kantasaria (Utah), Veronica Moore (Ohio), Rebecca Nick-Dart (Pennsylvania), Kristina Pasek (Wisconsin), Minal Patel (North Carolina), Danielle Patrick (Ohio), Katie Steffenhagen (Wisconsin)

Advisory Group on Communications and Public Affairs
Lindsey Kelley (Minnesota), Teresa Cavanaugh (Kentucky), Michael Decoske (South Carolina), Sarah Elliot (Washington), Guneeet Gandhi (California), Lindsay Garris (Maryland), Maria Giannakos (Ohio), Annie Hegg (South Dakota), Shannon Miller (New York), Marina Nikolavsky (Michigan), Majd Tanas (Washington), Nicole Weinert (South Carolina)

Advisory Group on Leadership and Career Development
Daryl Schiller (New York), Jennifer Cimnoch (Ohio), Amanda Davis (Minnesota), Christopher Fottler (South Carolina), Kelli Gibson (Colorado), Leslie Hamilton (North Carolina), Erin Hendrick (Colorado), Amy Hyduk (Indiana), Justin Konkoli (Oregon), Joel Marrs (Oregon), Brandon Orduway (Wisconsin), Stephanie Thune (Arizona)

Advisory Group on Professional Practice
Joshua Howell (Maryland), Scott Bergman (Illinois), Christine Conberg (Tennessee), Jillian Foster (Mississippi), Jennifer Jastrzembski (North Carolina), Julie King (Virginia), Jill Lacasse (New Hampshire), Joseph LaRochelle (Maryland), Aleshxe Martin (Kentucky), Melissa Meekins (Ohio), Carolyn Morton (Indiana), Andrea Seery (Georgia)

Advisory Group on Science and Research
Jeffrey Gildow (Nebraska), Lorry Buie (North Carolina), Ravish Choudhary (Oregon), Amy Dill (Ohio), Olga Hilas (New York), Jamie King (Nevada), Phillip Lal (Texas), Ali McBride (Arizona), Kimberly Pesuturo (Massachusetts), Sacha Pollard (Michigan), Marlintha Short (Kentucky), Kyle Weant (North Carolina)
ASHP Pharmacy Student Forum

In 2007, five new members were appointed to the ASHP Pharmacy Student Forum Executive Committee by the ASHP President. The Executive Committee is responsible for advising the ASHP Board of Directors and the ASHP staff on the overall direction of the Forum, including programs, member services, and activities. The Chair of the Executive Committee is an invited participant in strategic-planning meetings of the ASHP Board of Directors and also serves as the voting student representative to the ASHP House of Delegates. In addition, each Executive Committee member serves as Chair of one of the five Forum advisory groups.

The Executive Committee assists in building relationships between ASHP and the 103 colleges of pharmacy. The colleges of pharmacy are divided among the Executive Committee members, who serve as sources of information to the student society leadership on each campus. Communication is mostly via e-mail.

The 2007–2008 Executive Committee's strategic plan contained six goals: (1) increase students' knowledge about careers and trends in health-system pharmacy practice, (2) cultivate student professionalism, (3) improve the leadership skills of students, (4) enhance student involvement in the formation of ASHP policies, (5) monitor student membership needs and strive to meet them in ways consistent with ASHP priorities and resources, and (6) enhance collaboration among schools, affiliates, and ASHP in addressing the needs of students with respect to career information, leadership development, and organizational involvement. The five Student Forum advisory groups and the Executive Committee worked on many activities related to these priorities. This resulted in content for the ASHP website, personal visits to colleges of pharmacy, a two-hour Student Leadership session at the Midyear Clinical Meeting (MCM), and several suggestions for enhanced benefits and services for student members.

The Executive Committee gave special attention to the implementation of ASHP's new Student Society of Health-System Pharmacy (SSHP) Recognition Program, which aims to improve synergy between ASHP and its state affiliates in advancing the development of strong SSHPs and encouraging the pursuit of health-system pharmacy careers. The program has been very well received by students and faculty around the country. The application deadline for 2008–2009 ASHP Recognition is June 30, 2008.

The ASHP Pharmacy Student Forum continually strives to meet the needs of ASHP pharmacy student members. As in past years, 2007 continued the trend of a steady increase in Student Forum membership.

Advisory Groups. The Forum's five advisory groups were formed to increase opportunities for student leadership at the national level. Each member of the Forum Executive Committee serves as chair of one of the five committees: Meetings and Programming, Membership, Student Society and Leadership Development, Policy and Legislative Affairs, and Communications. In 2007, 50 students from the first through fourth professional years were appointed to these advisory groups. They met via conference call in October, and in person before the MCM in December. The groups communicate mostly via e-mail. One conference call is planned for spring 2008.

- The Meetings and Programming Advisory Group attended and evaluated all student sessions offered at the 2007 MCM. Members of the group provided constructive feedback on all of the student sessions and created proposals for three new sessions for the 2008 MCM.
- The Membership Advisory Group offered many suggestions about membership promotional materials, the packaging of residency information, communications from ASHP to members and prospective members, and communications between SSHPs.
- The Student Society and Leadership Development Advisory Group planned the program for the MCM student leadership session and offered suggestions to ASHP for meeting specific needs of SSHPs related to communications.

Executive Committee

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<thead>
<tr>
<th>Name</th>
<th>Location</th>
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<tbody>
<tr>
<td>Jamie Wilkins</td>
<td>Chair (Maryland)</td>
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<tr>
<td>Elaine Huang</td>
<td>Vice-Chair (Washington)</td>
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<td>John Hertig</td>
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<td>Jack Iskander</td>
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<td>Andrew Laegele</td>
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<td>Diane Ginsburg</td>
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- The Policy and Legislative Affairs Advisory Group contributed to the development of a resource center for SSHPs on planning a successful legislative day in state capitals and recommended strategies for educating students about the ASHP policy process and about high-priority health-system-related practice issues at the state and federal levels.
- The Communications Advisory Group recommended ways of increasing communication among SSHPs' leadership and in all student members of ASHP.

Clinical Skills Competition. The Twelfth Annual ASHP Clinical Skills Competition, held at the 2007 MCM, was a great success. This was the first year of a long-term partnership between ASHP and the ASHP Research and Education Foundation in support of this very visible and highly regarded program. Ninety-one colleges and schools of pharmacy throughout the nation competed in the two-day event. The national title was awarded to Cynthia Illy and Amy Kendrick of the University of Georgia College of Pharmacy. The program's written component and oral presentation format were updated in 2007 to reflect contemporary practice. The event offers students an opportunity to analyze actual patient cases, demonstrate their skills in assessing a patient's medical history, identify drug therapy problems and treatment goals, and recommend a pharmacist's care plan, including monitoring desired patient outcomes.

Meetings and Programming. Nearly 4000 pharmacy students from around the world attended the 2007 MCM. Students took advantage of the residency showcase, career development opportunities such as CareerFARM's Personnel Placement Service, and a full day of student programming. In addition to the student leadership session, the program included three sessions on residency training, a residency panel discussion, career roundtables, clinical cases for students, and sessions on CV and resume writing, enhancing interviewing skills, financial management, becoming engaged in the ASHP policy process, and how to effectively participate in a journal club.

Other MCM highlights included a student poster session and the 13th annual student society showcase, where 35 schools presented posters illustrating the activities of their SSHPs. All showcase participants received a complimentary copy of a popular ASHP drug information reference.

Communications. Each member of the executive committees of the Student Forum and the New Practitioners Forum committed to visiting at least one college of pharmacy to speak to students about ASHP membership, the importance of professional organization involvement, and how to become more engaged in professional activities at the local, state, and national level. Twelve executive committee visits are planned for the 2007–2008 academic year. The Student Forum looks forward to continuing this outreach effort and involving more ASHP member volunteers to address students in future years.

The twice-monthly ASHP NewsLink for Students continues to be a well-received mechanism for sharing information. It provides links to online information related to upcoming student deadlines; internship, experiential training, and career development opportunities; student programs; personal growth topics; and other items of interest. Student members of ASHP are automatically subscribed to this service as a member benefit.
ASHP Student Leadership Award Program. The ASHP Student Leadership Award Program prominently recognizes and celebrates the contributions of students who represent the very best attributes and accomplishments of ASHP student members. In a competitive process, a total of 12 students nationwide are selected annually for this recognition. Four student members in each professional year of pharmacy school, beginning with the second professional year, are selected to receive the award, which includes a plaque, an ASHP drug information reference library, and a cash award provided by the ASHP Research and Education Foundation and funded through the Walter Jone's Memorial Student Financial Aid Fund. The primary objective of the ASHP Student Leadership Award is to foster continued personal and professional development through a formal recognition program. Secondary objectives are to recognize student leader role models who have an interest in health-system practice and encourage student involvement in professional organizations.

The 2006–2007 ASHP Student Leadership Award recipients were as follows:

- Class of 2007: Ali McBride, University of Arizona; Veronica M. Moore, University of Cincinnati; Sacha R. Pollard, University of Southern Nevada; Majid-Teodore Tanas, Washington State University
- Class of 2008: Stephanie M. Carbone, Purdue University; Elizabeth A. Pang, Northeastern University; Tae Y. Kwa, Temple University; Jason Milton, University of Georgia
- Class of 2009: John J. Foley, Temple University; Elaine Y. Huang, University of Washington; Ashley Mains, Ohio Northern University; Suzanne L. Ray, University of Florida

Student Research Award. The Student Research Award of the ASHP Research and Education Foundation is presented to a pharmacy student for a published or unpublished paper or report of a completed research project related to pharmacy practice in a health system. The Foundation provides a plaque and an honorarium to the award recipient, as well as an expense allowance to attend the MCM to receive the award. The 2007 recipients were Gregory J. Welder, Timothy R. Wessel, M.D., Christopher B. Arant, M.D., Richard S. Schofield, M.D., and Issam Zineh, Pharm.D., who completed the project at the University of Florida in Gainesville, Florida. The project was titled "Complementary and Alternative Medicine Use among Individuals Participating in Research: Implications for Research and Practice."

Experiential Education Program. ASHP offers an elective rotation in national association management. The purpose of the experiential education program is to provide the student with an understanding of the importance of pharmacy associations to the profession and the value of participation in local, state, and national pharmacy organizations. The rotation provides an opportunity for undergraduate pharmacy students with an interest in association management to experience a professional association’s practices and procedures in furthering its mission, vision, and goals. The program also identifies potential leaders in the pharmacy profession. In the 2007–2008 academic year, ASHP hosted Brooke Emmmons from the University of Mississippi, Sarah Hilliber from Oregon State University, Kayla Hans from Drake University, Stephanie Ferrell from the University of South Carolina, Andrea Nedved from Drake University, and Viki Trakas from Drake University.

ASHP Summer Internship Program. The summer internship is a 10-week training program for a pharmacy student, with 1 week conducted at the ASHP Summer Meeting and 9 weeks at ASHP headquarters in Bethesda, Maryland. The program gives pharmacy students an opportunity to gain association experience in the specific areas of membership development and membership marketing at the national association headquarters and provides an understanding of the importance of pharmacy associations to the profession. The 2007 summer intern was Ma.-Chi Tran from the University of the Sciences in Philadelphia.

International Pharmaceutical Students’ Federation. The 53rd International Pharmaceutical Students’ Federation (IPSF) Annual World Congress was held in Taipei, Taiwan, August 6–16, 2007. As a member-in-association of IPSF, ASHP has an observer seat and floor privileges in the General Assembly at the annual congress. Kanal Patel from the University of Texas at Austin attended as ASHP’s representative in 2007.

Conclusion. The Forum had a successful year in 2007, marked by record membership growth, extensive student involvement, and the implementation of a plan to strengthen the relationship between ASHP and SSHPs across the nation. The ASHP Pharmacy Student Forum continually strives to meet the service and information needs of student members. This includes increasing awareness of career opportunities within health-system practice, providing information about residency training and other postgraduate education programs, enhancing student involvement in the development of ASHP policies, and encouraging professional development by fostering student involvement in ASHP and state and local health-system pharmacy organizations.

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