



# House of Delegates Session—2009

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## Board of Directors Reports on Councils

ASHP councils met in Bethesda, Maryland, September 23–24, 2008.

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.

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### Policy Recommendations

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# House of Delegates Session—2009

## 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.

James G. Stevenson, Board Liaison

### **Council Members**

Rafael Saenz, Chair (Pennsylvania)  
Miriam M. Smith, Vice-Chair (Illinois)  
Kathleen H. Besinque (California)  
Angela L. Bingham, Student (South Carolina)  
Philip W. Brummond, New Practitioner (Wisconsin)  
Kathryn M. Clark (Ohio)  
Michael B. Cockerham (Louisiana)  
Dianna L. Gatto (Washington)  
William L. Greene (Tennessee)  
Gerald E. Meyer (Pennsylvania)  
Natasha C. Nicol (South Carolina)  
Douglas J. Scheckelhoff, Secretary

### **Policy Recommendations**

#### **A. Pharmacy Student Experiences in Medically Underserved Areas**

- 1 To encourage colleges of pharmacy to require student
- 2 learning experiences in traditionally medically under-
- 3 served areas and with diverse patient populations.

#### **Background**

The Council believed and the Board agreed that students would benefit from experiential rotations in rural and urban settings, especially in settings or areas classified as medically underserved. Numerous published reports have shown how such rotations provide value to both the site and the student. Students learn about the cultural, financial, language, and other challenges encountered in these settings, and these skills are often invaluable when they enter practice. In addition, it is not uncommon that a student's exposure to a new practice area results in great interest and ultimately in a career choice that might otherwise not have been considered.

The Council did not support the idea of a recommendation that would mandate rotations in these settings, since there are many ways to provide the interaction. Concern was also raised over how colleges develop an infrastructure for providing these experiences. The challenges of finding good teaching sites in these settings are formidable and include the limited number of sites, a lack of qualified preceptors, and geographic distances from the college that result in housing needs. Council members noted that the outcome of the educational experience is dependent on the quality of the preceptor, which is highly variable in these settings.

Current requirements of the Accreditation Council for Pharmacy Education (ACPE) call for colleges of pharmacy to ensure that graduates can provide patient-centered care that addresses cultural diversity. Although experiential rotations may be the most common way for students to be exposed to diverse patient populations,

the Council discussed many other creative ways in which this is being accomplished. Some colleges, for example, require students to perform service learning projects with a focus on underserved populations.

#### **B. Medication Safety Related Education in U.S. Colleges of Pharmacy**

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

#### **Background**

The Council believed and the Board agreed that pharmacists play an important role in developing safe systems for medication use and in preventing medication errors. Unfortunately, most pharmacy curricula do not contain dedicated courses on medication safety. The Council believed this issue is so important that ASHP should recommend that all students receive this training while in pharmacy school. Students should learn about safety principles from a qualified instructor and should be encouraged to apply their learning about safe systems during their experiential rotations. Experiential preceptors should encourage students to identify flaws in the system and recommend changes.

Students often enter experiential rotations with limited knowledge about medication error prevention, a safety culture, or how to apply generally accepted safe practices. Council members noted that the need for medication safety awareness and error prevention touches every pharmacist, regardless of practice setting. Pharmacy students should learn of their professional obligation to provide medications in the safest possible manner before they enter practice. Pharmacy students often believe that they must work within the system of medication use they find themselves in and do not feel empowered

to identify safer processes. Council members noted that preceptors often do not teach safety or encourage students to look for potential improvements. One way to incorporate medication safety would be to give students projects that help develop their ability to analyze medication-use systems for error reduction potential.

The Council discussed existing ASHP policy 0608, Interdisciplinary Health Professions Education. Although policy 0608 was considered to still be relevant, its focus is on the importance of interdisciplinary education, with only a mention of patient safety. The Council concluded that a separate policy is needed to stress the importance of this educational focus.

Council members suggested that ASHP should develop materials (e.g., textbooks, video materials) for use in such a course, since teaching resources are limited. Council members believed a standard curriculum for a medication safety course is needed. It was noted that the American Association of Colleges of Pharmacy (AACP) is developing a model curriculum in this area and there would be value in collaborating on that effort.

### C. Pharmacy Expertise in the Preparation and Handling of Injectable Medications

1 To encourage colleges of pharmacy to include sterile  
2 compounding and aseptic technique instruction in the  
3 didactic curriculum and during experiential education;  
4 further,

5 To support the development of postgraduate, curriculum-  
6 based sterile compounding training programs to foster  
7 an increase in the number of pharmacists with sterile  
8 compounding expertise.

#### Background

The Council believed and the Board agreed that injectable medications and biologics will continue to be a significant aspect of treating patients. The Council agreed that there is a clear need for students to have a basic understanding of sterile compounding upon graduation. The Council also believed that the complexity of intravenous therapy, the risk of errors or patient harm, and new biologic therapies all demand a higher level of expertise in sterile compounding in the pharmacy.

USP Chapter 797 and other efforts have increased the focus on the quality of injectable medication preparation and have caused organizations to improve staff training, facilities, and procedures used. Some pharmacy departments give high priority to the quality of injectable medications, while others have reluctantly adopted USP 797 and ASHP guidelines. The Council discussed two needs related to pharmacy expertise in sterile product preparation: the baseline training and knowledge of the new pharmacy graduate and the need for pharmacists with an advanced body of knowledge on sterile product preparation, especially in pharmacy departments where complex sterile preparations are compounded.

Education in colleges of pharmacy on sterile compounding varies greatly. Some Council members noted that some students learn to compound intravenous admixtures proficiently by spending time working in a hospital pharmacy. Others cited examples in which students graduate without ever handling or touching an intravenous solution.

The Council also discussed the need for pharmacists who have additional training in sterile compounding beyond baseline knowledge. Many pharmacy departments, especially in larger hospitals, have a staff member who works in this capacity. Often these individuals have developed their expertise over time and will be retiring soon. Rarely is there anyone ready to step into this role, and training opportunities are limited.

The Council agreed that sterile product experts should receive more extensive training beyond simple aseptic technique. The Council suggested that ASHP seek ways to develop a model that combines classroom instruction with hands-on experience and exposure to facility design and equipment.

### D. Continuing Professional Development

1 To endorse and promote the concept of continuing pro-  
2 fessional development (CPD), which involves personal  
3 self-appraisal, educational plan development, plan imple-  
4 mentation, documentation, and evaluation; further,

5 To continue the development of a variety of mechanisms  
6 and tools that pharmacists can use to assess their CPD  
7 needs; further,

8 To encourage individual pharmacists to embrace CPD  
9 as a means of maintaining their own professional com-  
10 petence; further,

11 To encourage pharmacy managers to promote CPD as  
12 the model for ensuring the competence of their staff;  
13 further,

14 To collaborate with other pharmacy organizations, state  
15 boards of pharmacy, accrediting bodies, and regulatory  
16 bodies in the development of effective methods for  
17 implementing CPD; further,

18 To strongly support objective assessment of the impact  
19 of CPD on pharmacist competence; further,

20 To endorse the efforts of colleges of pharmacy and ASHP-  
21 accredited pharmacy residency programs to teach the  
22 principles, concepts, and skills of CPD.

(Note: This policy would supersede ASHP policy 0408.)

#### Background

During sunset policy review, the Council voted to recommend amending ASHP policy 0408 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To endorse and promote the concept of continuing professional development (CPD), which involves personal self-appraisal, educational plan development, plan implementation, documentation, and evaluation; further,

To continue ~~strongly encourage~~ the development of a variety of mechanisms and tools that pharmacists can use to assess their CPD needs; further,

To encourage ~~support the efforts of~~ individual pharmacists to embrace CPD as a means of maintaining their own professional competence ~~understand CPD (including the fact that various options are available for self-assessment) and to implement CPD~~; further,

To encourage pharmacy managers to promote CPD as the model for ensuring the competence of their staff; further,

To collaborate with other pharmacy organizations, state boards of pharmacy, accrediting bodies, and regulatory bodies in the development of effective methods strategies for implementing ~~piloting the implementation of~~ CPD; further,

To strongly support objective assessment of the impact ~~outcomes of implementation~~ of CPD on pharmacist competence; further,

To encourage ~~endorse the efforts of~~ colleges of pharmacy and ASHP-accredited pharmacy residency programs to teach the principles, concepts, and skills of CPD.

The Council supported and the Board agreed with the intent of policy 0408 but concluded that it should be revised to further emphasize the importance of CPD and personal responsibility in lifelong learning. The Council discussed establishing a target date (e.g., 2015) for full adoption of CPD principles. The Council also discussed whether CPD should be required by state licensing boards under another agenda topic (see Board Actions below).

### E. Pharmacy Residency Training

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

(Note: This policy would supersede ASHP policy 9911.)

#### Background

The Council discussed existing ASHP policy 9911 regarding phar-

macy residency training. The Council considered the policy to be relevant but chose to amend it to recognize ASHP accreditation and broaden the scope of benefits that come from residency training. The promotion of residency training to pharmacy students, contained in the second paragraph of the policy, was reviewed and considered to be already addressed by existing ASHP policy 8507.

During sunset policy review, the Council voted to recommend revising ASHP policy 9911 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

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

~~To expand efforts to make pharmacy students aware early in their education of the career choices available to them and the importance health-system employers attach to the completion of a residency.~~

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### Board Actions

#### Pharmacy Student Experiences in Medically Underserved Areas.

The Council recommended and the Board voted

To foster innovative models for involving pharmacy students in the provision of care to medically underserved populations; further,

To publish and promote best practices, tools, and resources supporting pharmacy student education and preceptor development in the provision of pharmacist services to underserved populations.

As part of the Council's discussion on student learning experiences in traditionally medically underserved areas and with diverse patient populations (Policy Recommendation A), ways to support development of teaching sites in underserved areas were also discussed, including preceptor development and finding ways to remove barriers to having students in these settings. Since these sites often have unique locations and limited resources, methods of placing and teaching students may also be non-traditional. The development of these types of experiences will be accelerated if new, innovative models can be developed and information about resources and best practices is made available to help remove barriers to these pharmacy student experiences.

#### Continuing Professional Competence.

The Council recommended and the Board voted

To explore the implications of requiring mandatory continuing professional development with periodic assessment to maintain pharmacist licensure.

The Council discussed the need for all health professionals to maintain professional competence throughout their careers. Nearly all health professions are developing a more rigorous means of ensuring continuing competence, usually through state licensing boards. Pharmacy continues to use initial licensure based on successful completion of the NAPLEX exam, supplemented by traditional continuing education, as a basis for establishing and maintaining competence. The Council discussed this model of "licensure for life," with its minimal requirements for continuing education, and did not consider it to be adequate for the future, especially with the growing complexity of medication use and the need for safe and effective patient care.

CPD was discussed as a way to provide structure to lifelong learning. If used as intended, CPD can be an effective model for maintaining competency. A needs assessment and individualized development plan using a portfolio subject to external review was viewed as a good model. Although CPD is endorsed by many in the profession, including ASHP, its voluntary nature has resulted in

minimal adoption by individual practitioners. The Council believed that unless state licensing boards set defined requirements, perceived issues related to a lack of accountability and consistency will only continue. The Council believed more information and analysis are needed before a specific policy recommendation can be made.

#### Competence of Pharmacists Re-entering Practice or Changing Practice Settings.

The Council recommended and the Board voted

To evaluate the feasibility of and need for establishing a requirement for re-entry training for pharmacists who have a time lapse in practice or change pharmacy practice settings.

The Council discussed the changing demographics of the pharmacy workforce and how a gender shift in the profession has resulted in a growing number of pharmacists leaving practice for a period of time during their career or working less than full-time. With the growing complexity of medication use, expanding body of literature, and release of new drug products, it is increasingly difficult for pharmacists to maintain their competence, much less re-enter practice after an extended absence. Currently, state boards of pharmacy require only that a pharmacist earn continuing education credits to maintain his or her license. The Council discussed how other health professions, such as nursing and medicine, have developed educational courses tailored to those re-entering practice. Many state licensing boards have also established requirements for an approved refresher course before professionals can re-enter practice after a defined period of time away.

There was strong Council support for requiring a structured educational program for those re-entering practice. However, the Council believed more information is needed to determine how long a practice lapse would require such a program; the depth, scope, and format of the re-entry program; and how the program might be managed. The Council also believed a better understanding of the number of individuals who would be eligible for such a program is needed.

The Council believed this is an extremely important issue because of the pharmacist's role in direct patient care and the need to ensure the safe provision of care. It was suggested that ASHP staff study the issue and bring it back to the Council for further consideration.

**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.)

- Cultural Diversity Among Health Care Providers (0409)

## Other Council Activity

**ASHP Statement on Continuing Education.** The Council voted

To revise the ASHP Statement on Continuing Education.

As part of sunset review, the Council discussed the ASHP Statement on Continuing Education. The Council believed that the statement includes many important components relevant to continuing education but that it should be revised to include current philosophies and policies related to continuing education, including active learning and continuing professional development.

**Competence and Capacity of the Pharmacy Workforce to Care for an Aging Population.** The Council discussed data projecting significant growth in the number of persons age 65 and older in the coming years. Currently, one third of all prescriptions are consumed by this population, and that proportion is expected to increase in the future. The Council discussed the need for pharmacists to have a broader knowledge of the health care issues and pharmaceutical needs of the elderly.

The Council discussed both the need for all pharmacists to have a greater understanding of issues related to caring for geriatric patients and the need for more pharmacy specialists who specifically care for elderly patients who are frail. The distinction is clear, since many aging baby-boomers are not frail but could still benefit from having a pharmacist who is competent in geriatric therapeutics.

ACPE curricular standards and guidelines for colleges of pharmacy include geriatrics as a special population area to be covered, but the guidelines do not specify the depth, breadth, or quantity of geriatrics-focused education and training.

It was suggested that ASHP work collaboratively with other pharmacy associations, especially the American Society of Consultant Pharmacists, on possible professionwide solutions, since pharmacists in all settings provide care for geriatric patients.

**Models for Evaluating Professional Credentials for Pharmacists.** The Council discussed the numerous credentials available for pharmacists beyond the academic pharmacy degree and state licensure, such as residency training and specialty certification. Many credentials are specific to pharmacy, but a growing number are multidisciplinary. Increasingly, pharmacy credentials are being used as part of a privileging process within hospitals and health systems to verify competencies and to define scope of practice. In addition, new models for payment for pharmacists' professional services are being developed, and some require the pharmacist to demonstrate competence by attaining certain credentials in order to become eligible for payment.

Council members described situations in which members of their staff had sought certificates or other credentials from unknown organizations. These credentials were not recognized by the profession and were of unknown quality. Council members found it very difficult to determine the value of these programs, and managers and others charged with ensuring competence of practitioners were left in a similarly difficult situation.

The need for a more structured way to evaluate the different credentials available was discussed. The Council reviewed the criteria developed by the Commission on Credentialing in Pharmacy (CCP) and published in *CCP Guiding Principles for Certification of Individuals in Pharmacy* and concluded that they were sound. However, publication of the criteria has not led to universal adoption and does not in itself provide the framework for a credible credentialing model. The Council strongly believed that the appropriate credentials for different levels of advanced practice and activities should be determined by the profession, not by the government or some outside body. The role CCP plays in that determination has not been clear.

The Council recommended that ASHP play an active role in developing a model for credentialing requirements that would be accepted professionwide.

**Pharmacy Experiential Education.** The Council discussed the results of a national survey conducted by ASHP and AACP related to experiential education. Much of the discussion focused on whether there will be adequate capacity for experiential education.

The Council discussed the role ASHP could play in helping enable health systems to establish an experiential site or expand an existing site. For example, guidance could be provided on how to establish an affiliation agreement and related logistical issues, how to prepare and promote resident involvement in teaching, and how to demonstrate to hospital administration the value of providing student rotations.

The Council agreed that the success of experiential rotations is often tied to how students are utilized. There must be a balance between the service students provide to the organization and the opportunity the organization offers students to learn about practice and build their knowledge. Successful sites find ways to serve both purposes simultaneously. The need for student schedules and college calendars to align with patient care needs was also noted. It is often difficult to establish a meaningful role for students when they are available on a very limited and sporadic basis. It was suggested that ASHP identify and promote examples of successful practice models that have integrated students into pharmacy services and patient care.

**Expanding Access to Accredited Pharmacy Technician Training Programs.** Current ASHP policy calls for standardized education and training of pharmacy technicians in ASHP-accredited training programs. However, the capacity of such programs is very limited and would need to be greatly increased for this vision to become a reality. The Council discussed what ASHP could do to encourage more hospitals to comply with training standards and seek accreditation of their training programs. Also discussed were whether colleges of pharmacy could be a source of training and education for pharmacy technicians and whether ASHP or state affiliates could offer a base curriculum to facilitate quality technician training.

The Council recommended that ASHP create and make available the modules and tools needed to develop a quality technician training program within hospitals that would meet ASHP-accreditation standards. This would help sites improve the training they offer and would help remove barriers to becoming accredited by ASHP.



# House of Delegates Session—2009

## Board of Directors Report on the Council on Pharmacy Management

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

Kathryn R. Schultz, Board Liaison

### Council Members

Jennifer E. Tryon, Chair (Oregon)  
Eugene A. Handza, Vice-Chair (Kansas)  
Paul J. Barrett (Maine)  
Robert DeChristoforo (Maryland)  
Jennifer V. Kacmarcik, New Practitioner (Maryland)  
Todd A. Karpinski (Texas)  
Thomas E. Kirschling (Pennsylvania)  
Nancy A. Konieczny (Missouri)  
Donald H. Lynx (Texas)  
Dawn M. Moore-Jefferson (Indiana)  
Judith K. Schneider (Minnesota)  
Mai-Chi N. Tran, Student (Pennsylvania)  
Steven S. Rough, Section of Pharmacy Practice Managers Liaison (Wisconsin)  
Kathryn R. Schultz, Board Liaison  
David R. Witmer, Secretary

### Policy Recommendations

#### A. Pharmacist Leadership of the Pharmacy Department

- 1 To affirm the importance of an organizational structure in hospitals and health systems that places administrative, clinical, and operational responsibility for the pharmacy department under a pharmacist leader; further,
- 5 To affirm the role of the pharmacist leader in oversight and supervision of all pharmacy personnel; further,
- 7 To recognize the emerging role of nonpharmacists in leadership and management roles in pharmacy departments.

(Note: This policy would supersede ASHP policy 0606.)

#### Background

The Council reviewed ASHP policy 0606 and voted to recommend amending the policy as follows (underline indicates new text):

To affirm the importance of an organizational structure in hospitals and health systems that places administrative, clinical, and operational responsibility for the pharmacy department under a pharmacist leader; further,

To affirm the role of the pharmacist leader in oversight and supervision of all pharmacy personnel; further,

To recognize the emerging role of nonpharmacists in leadership and management roles in pharmacy departments.

The Council believed and the Board agreed that ASHP's policy on leadership of the pharmacy department should be expanded to recognize the growth of leadership roles of nonpharmacists. The Council also saw the need to affirm the importance of a pharmacist as the leader of the pharmacy enterprise and the role of this pharmacist leader in the supervision and management of all pharmacy personnel.

The Council discussed the increasing complexity of managing medication use and the expanding roles for nonpharmacists in achieving the mission of the pharmacy department. The Council reviewed the ASHP Long Range Vision for the Pharmacy Work Force in Hospitals and Health Systems and ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive. ASHP's Long Range Vision describes a growing role for nonpharmacists in management and leadership positions in hospitals and health systems. The Council and Board agreed that there will be expanded use of nonpharmacists in management and leadership roles in the future. Many factors will fuel this expansion, including a shortage of pharmacists, pharmacists' salaries, and the growing complexity of the pharmacy operation.

The Council believed and the Board agreed that there are many functions in the pharmacy department that can be led or managed by nonpharmacists. Some examples are supervision of technicians and management of technological, business, and financial matters. The Council distinguished between management, leadership, and supervision, noting that unique management roles do not necessarily imply a supervisory function. The Council also recognized that the use of such specialized nonpharmacist expertise will vary depending on the size and complexity of the pharmacy enterprise. These roles will be more prevalent in large facilities and less so in small or rural facilities, where there is likely to be less specialization in pharmacy functions. Therefore, the Council believed and the Board agreed that ASHP should not advocate that certain roles be

filled by nonpharmacists but instead should encourage members to share examples of innovative roles for nonpharmacists through education, publications, and networking forums.

The Council also discussed roles that should be filled by pharmacists. The Council emphasized the continuing need to utilize technology and well-trained technicians to allow pharmacists to become more fully engaged in patient care. The Council believed education and training as a pharmacist is critical for roles in the management of patient care functions. Since the director or the chief pharmacy officer is responsible for the management of all aspects of the pharmacy service, the Council also believed that the education and training of a pharmacist is essential for that position.

## **B. Medication Errors Related to Intimidating and Disruptive Behaviors**

- 1 To affirm the professional responsibility of the pharmacist to ensure patient safety by communicating with
- 2 other health professionals to clarify and improve medication orders; further,
- 3
- 4
- 5 To advocate that hospitals and health systems adopt
- 6 zero-tolerance policies for intimidating or disruptive
- 7 behaviors; further,
- 8
- 9 To encourage hospitals and health systems to develop
- 10 and implement education and training programs for
- 11 all health professionals to encourage effective communication and discourage intimidating or disruptive
- 12 behaviors; further,
- 13
- 14 To encourage colleges of pharmacy and residency training
- 15 programs to incorporate training in communications and managing intimidating or disruptive behaviors; further,
- 16
- 17 To collaborate with other organizations to advocate
- 18 codes of conduct that minimize intimidating or disruptive behavior in hospitals and health systems.

### **Background**

The Council discussed the role of intimidating and disruptive behaviors as contributing factors in medication errors. A July 9, 2008, sentinel event alert from The Joint Commission (TJC) titled "Behaviors That Undermine a Culture of Safety," summarizes the impact of these behaviors. Intimidating behavior can lead to medical errors, contribute to poor patient satisfaction, increase cost, and result in staff turnover. The alert notes that disruptive behaviors can range from passive behaviors such as refusal to answer questions or return pages and use of condescending language to overt actions such as verbal outbursts or physical threats. TJC has a new leadership standard (LD.03.01.01) that will become effective January 1, 2009. This new standard has two elements of performance (EP):

EP 4: The hospital/organization has a code of conduct that defines acceptable and disruptive or inappropriate behaviors.

EP 5: Leaders create and implement a process for managing disruptive and inappropriate behaviors.

TJC also suggests education of all team members on appropriate professional behavior as defined by the organization's code of conduct, the creation of zero-tolerance policies for intimidating or disruptive behaviors, medical staff policies specifically addressing disruptive or intimidating behaviors, protections for those who report instances of intimidation, skills-based training, and an organizational process for addressing disruptive behaviors.

The Council also reviewed two medication safety alerts and a 2003 survey on workplace intimidation by the Institute for Safe Medication

Practices (ISMP). In ISMP's survey of 2095 hospital health care providers, 88% of respondents had encountered condescending language, 79% had encountered a reluctance or refusal to answer questions or phone calls, 48% had been subjected to strong verbal abuse, and 4% reported actual physical abuse. Intimidating behavior was not limited to physicians or prescribers. Nearly half (49%) of the respondents reported that experience with intimidation altered the approach to order clarifications or questions about medication orders, increasing the intimidated professional's reluctance to intervene.

There has been growing attention to this issue, especially by the nursing profession, with results such as the universal protocol and time-outs to prevent wrong site, wrong procedure, or wrong person surgery. However, pharmacy has given little attention to this issue. The Council believed and the Board agreed that it is important to encourage organizational efforts targeting all professionals and not just physicians. The Council also believed and the Board agreed that organizations should develop training programs to discourage disruptive behaviors and to train employees in handling disruptive situations, and it encouraged ASHP to address this through journal articles or the development of educational programs or products to assist in the provision of training in health care facilities. The Council believed and the Board agreed that it is important to encourage colleges of pharmacy and residency training programs to provide training in this area. The Council suggested that the issue of intimidation as a contributing factor in medication errors should be incorporated in the ASHP Guidelines on Preventing Medication Errors in Hospitals, and it encouraged the Council on Pharmacy Practice to modify the document accordingly.

## **C. Standardized Clinical Drug Nomenclature**

- 1 To encourage federal agencies, the pharmaceutical industry,
- 2 pharmacy and medical software providers, and
- 3 purveyors of clinical data repositories and drug databases
- 4 to explore the potential benefits of supplementing or
- 5 modifying the National Drug Code with a coding system that can be used effectively to support patient care,
- 6 research, and financial management; further,
- 7
- 8 To encourage that such a coding system encompass pre-
- 9 scription drug products, nonprescription medications,
- 10 and dietary supplements and include both active and
- 11 inactive ingredients.

(Note: This policy would supersede ASHP policy 0801.)

### **Background**

In response to a Recommendation from the ASHP House of Delegates, the Council assessed the need for expanding the concept of numerical classification or coding in ASHP's existing policies. The Council voted to recommend amending ASHP policy 0801 as follows (underline indicates new text):

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 to support patient care, research, and financial management across the medication use continuum; further,

To encourage that such a coding system encompass prescription drug products, nonprescription medications, and dietary supplements and include both active and inactive ingredients.

Clinical decision support systems (CDSS) in computerized provider order entry (CPOE) systems and pharmacy information systems have been widely used for screening drug interactions and patient allergies. For this screening to be effective, a baseline coding structure of the medications must be available. Discussion at the June 2008 session of

the ASHP House of Delegates suggested the need for expansion of this coding system to include drug excipients and herbal products.

The National Committee on Vital and Health Statistics (NCVHS) has recommended changes to give the Food and Drug Administration (FDA) full control over the National Drug Code (NDC). Currently, FDA controls only a portion and manufacturers control the remainder. FDA has made recommendations for uniform standards to enable electronic prescribing (e-prescribing) in ambulatory care. During the past several years, NCVHS has focused considerable attention on the feasibility and desirability of standards to support e-prescribing and the need for standard terminology for clinical drugs to facilitate automated drug-use review and decision support for patient safety. In previous reports, NCVHS documented NDC shortcomings, most notably concern about perceived weaknesses of the current NDC database and linkage of the NDC to RxNorm concepts. NCVHS expressed the need for harmonization of terminologies to eliminate incompatibilities that impair drug utilization studies and may negatively affect patient safety. RxNorm, a standardized nomenclature for clinical drugs, is produced by the National Library of Medicine. In RxNorm, the name of a clinical drug combines its ingredients, strengths, and form. RxNorm has limitations; it does not identify a product's excipients, and it does not include herbal products or nonprescription medications.

The Council noted that policy 0808 advocates the inclusion of excipients in the official product labeling for drugs and policy 0811 advocates disclosure of excipients in dietary supplement labeling. However, ASHP policy 0801 does not specifically identify excipients as critical elements of a coding system; that policy is limited to drug products. The Council amended policy 0801 to encompass prescription drug products, nonprescription medications, and dietary supplements and to include both active and inactive ingredients. The Council believed and the Board agreed that without the inclusion of these elements in a coding system, the effectiveness of CDSS for screening medication orders will be limited.

#### D. Pharmacist's Role in Health Care Information Systems

- 1 To strongly advocate key decision-making roles for
- 2 pharmacists in the planning, selection, design, imple-
- 3 mentation, and maintenance of pharmacy informa-
- 4 tion systems, electronic health records, computerized
- 5 provider order entry systems, and e-prescribing systems
- 6 to facilitate clinical decision support, data analysis, and
- 7 education of users for the purpose of ensuring the safe
- 8 and effective use of medications; further,
- 9 To advocate for incentives to hospitals and health sys-
- 10 tems for the adoption of patient care technologies.

(Note: This policy would supersede ASHP policy 0203.)

#### Background

The Council discussed ASHP policies related to e-prescribing and voted to recommend amending ASHP policy 0203 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To strongly advocate key decision roles of pharmacists in the planning, selection, design, implementation, and maintenance of ~~electronic patient information systems (including computerized prescriber order entry systems)~~ pharmacy information systems, electronic health records, computerized provider order-entry systems, and e-prescribing systems to facilitate clinical decision support, data analysis, and education of users for the purpose of ensuring the safe and effective use of medications; further,

To advocate for incentives to hospitals and health systems for the adoption of patient-care technologies.

E-prescribing is similar in some respects to computerized provider order entry, but it is often less complicated and may stand alone from the electronic health record (EHR). The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) established a five-year program of incentive payments to eligible professionals who are "successful electronic prescribers." Successful prescribers are those who either report applicable electronic prescribing measures established under the Physician Quality Reporting Initiative or electronically submit prescriptions under Medicare Part D at a level determined by the Centers for Medicare & Medicaid Services (CMS). The incentive payment program begins in January 2009. A conference will be held to educate affected constituencies on the MIPPA program and CMS's plans for implementation. With the increased adoption of and government incentives for e-prescribing, hospitals and health systems may be involved in implementing a system in their ambulatory care areas.

The Council believed there would be many benefits to the widespread adoption of e-prescribing. Widespread use of e-prescribing could support the achievement of The Joint Commission's National Patient Safety Goals and could help to achieve more effective medication reconciliation. The Council noted, however, that standards for e-prescribing are still evolving and many pharmacies still are not equipped to effectively capitalize on the benefits of e-prescribing.

The Council reviewed ASHP policy 0203 and believed that use of the term "patient information systems" is not clear and that the policy does not adequately define the key elements of a prescribing system. The Council amended the policy to clarify that the policy applies to CPOE, EHRs, pharmacy information systems, and e-prescribing. The Council also believed that ASHP should advocate for incentives for hospitals and health systems to implement e-prescribing. The Council also noted that the U.S. Drug Enforcement Administration needs to address the regulation of electronic prescriptions for controlled substances, and it encouraged the Council on Public Policy to address this issue.

#### Board Actions

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

- Scope and Hours of Pharmacy Services (0403)
- Standardization, Automation, and Expansion of Manufacturer-Sponsored Patient-Assistance Programs (0404)
- Workload Monitoring and Reporting (0406)
- Documentation of Pharmacist Patient Care Services (0407)
- Fostering Pharmacy Leadership (9901)
- Compliance with Governmental Payment Policies (9902)
- Optimizing the Medication-Use Process (9903)

## Other Council Activity

**Pharmacy Perioperative Services.** At the request of the Section of Pharmacy Practice Managers, the Council discussed the desirability of efforts to expand pharmacy services in the perioperative area. The Council believed expansion of the pharmacist's role in the perioperative area would provide significant opportunities for education, improving cost capture, control of waste, management of controlled substances, and clinical consultation. The Council believed that the perioperative area presents opportunities for pharmacists to improve patient care, but it also believed that pharmacy services to the perioperative area are highly variable and that pharmacy leaders should be encouraged to assess pharmacy practice in their institutions to identify high-risk areas where expansion of pharmacists' services could improve patient care.

The Council reviewed the ASHP Guidelines on Surgery and Anesthesiology Pharmaceutical Services. The guidelines were developed in 1998. The Council believed the guidelines should be updated, and it encouraged the Council on Pharmacy Practice to revise the document. The focus of the current guidelines is on operating room satellite pharmacies. The Council believed that the document should be updated with a focus on the role of the pharmacist in improving patient safety and should increase its focus on pharmacy services to the perioperative area rather than describing a satellite pharmacy structure. The Council also encouraged ASHP to identify and showcase new models of pharmacy service to the perioperative area and to provide education and training to assist pharmacy leaders in cost justification of perioperative pharmacy services.

**Telepharmacy as Equivalent to Pharmacists' Order/Medication Review.** In response to a Recommendation from the ASHP House of Delegates, the Council discussed the desirability of promoting telepharmacy as an alternative to pharmacists' on-site review and evaluation of medication orders. The Council strongly believed that, when feasible, it is desirable for pharmacists to be present in a practice setting in physical proximity to patients, physicians, nurses, and other health care personnel. The Council believed that this enhances effective communication and that working directly with patients and other caregivers encourages the development of professional relationships that help facilitate practice. However, the Council also noted that telepharmacy is an effective tool that can be used to provide access to the services of pharmacists when 24-hour on-site pharmacist services are not practical.

The Council discussed a variety of potential applications of telepharmacy to support medication order review, including supporting 24-hour access, providing access to pharmacists in rural and underserved areas, supporting work-from-home arrangements for pharmacists, and providing access to specialist pharmacist services. The Council supported the use of telepharmacy to increase the provision of pharmacist services when on-site service is not feasible, but it did not support expanding the use of telepharmacy to accommodate telework preferences.

The Council reviewed ASHP policies 0712, 0716, and 0403 and did not suggest changes to these policies. ASHP policy 0403 supports the use of remote review of medication orders when on-site pharmacist review is not available. The Council also reviewed draft ASHP Guidelines on Remote Medication Order Processing and believed that this document will provide useful guidance to ASHP members when completed. The Council suggested broadening the description of the areas of current use of telepharmacy in the document. The Council believed that standards should not be compromised to accommodate telepharmacy and that standards of care should apply equally to on-site and telepharmacy practice.

**Use of Clinical Decision Support to Limit Near-Universal Pharmacist Order Review.** In response to a Recommendation from the ASHP House of Delegates, the Council discussed the desirability of using clinical decision support systems (CDSS) to limit universal pharmacist order review. The Council discussed the current status of CDSS. According to a 2007 ASHP survey only 12% of US Hospitals have implemented CPOE with a robust CDSS. Up to 90% of hospitals are looking at this technology in the next three

years. While every CPOE computer system includes commercially developed CDSS, extensive local customization is required to achieve optimal performance and patient outcomes. When implemented and properly customized with dedicated pharmacist resources there is substantial evidence that CDSS can have positive patient outcomes. However, the extensive customization required by these systems has limited the widespread use of CDSS, especially for the purpose of limiting pharmacists' review of medication orders.

The Council supported further research and pilot projects to demonstrate the value of CDSS. Research validating CDSS algorithms, as well as human factors research in the application of CDSS, would be valuable. The impact of CDSS on the pharmacist review of orders should be aggressively evaluated. The Council did not support the use of CDSS to replace pharmacist review of medication orders at this time. The Council did not believe that the technology has evolved to a point where it could replace the pharmacist's role in medication review. The Council also did not think it would be wise to create policy that conflicted with Joint Commission requirements for pharmacist medication order review. The Council did support the use of CDSS to improve medication use, believing that there may be more value in focusing efforts on the use of CDSS in improving the use of high-risk medications.

**Centralized Distribution Services.** In response to a Recommendation from the ASHP House of Delegates, the Council discussed the desirability of promoting increased centralization of distributive pharmacy functions to improve the efficiency of logistical functions and expand patient care opportunities for pharmacists. The Council discussed advantages and potential disadvantages of centralizing pharmacy distribution services. A centralized approach has the potential to increase efficiency of the distribution process, but there are risks associated with placing all pharmacy distribution in one facility. The Council noted that natural disasters such as hurricanes and earthquakes can damage infrastructure and disrupt delivery channels. Recent hurricanes and bridge collapses were noted as examples of events that can have a negative impact on centralized distribution. It is important to plan for contingencies and build redundancy into distribution models to ensure that patient care can still be delivered in an emergency. The U.S. Department of Veterans Affairs (VA) Centralized Mail Order Pharmacies (CMOPs) model was described. CMOPs process 70–80% of the entire VA outpatient national prescription workload, filling 100 million prescriptions annually. In the design of the CMOPs, redundancy was a very important feature; all operations can be transferred to another CMOP in the event that one facility can no longer function.

The Council believed that well-designed centralized distribution models with appropriate control measures could generate efficiencies, especially in corporately related hospitals. The Council believed that the most significant barrier to the implementation of centralized distribution models is state laws and regulations. Even corporately related hospitals face challenges when distribution crosses state lines. The Council reviewed ASHP policy 0522 and concluded that it generally addresses the issue but does not specifically describe centralized distribution models. The Council believed that the Council on Public Policy should review this issue and assess whether ASHP policy sufficiently addresses state regulation of centralized distribution models.

**Compromises in Medication-Use Standards Due to Manpower Shortages.** The Council discussed the impact of pharmacist shortages on the implementation of medication-use standards. The Council believed that manpower shortages are only one factor affecting the implementation of standards. An additional challenge is keeping pace with the expansion of standards by various groups, including The Joint Commission, CMS, the United States Pharmacopeia (USP), payers, and ASHP. The growing number of pharmacy schools and increasing enrollments in pharmacy schools are also placing greater demands on limited pharmacy manpower. Overall, the Council believed that the demand for pharmacists' services is exceeding the capacity to deliver them. The Council expressed

concern that as pharmacy leaders try to manage to meet standards, they may be losing sight of the desired outcome of improved quality that underlies the standards.

The Council noted that resource requirements are often not considered in the development of new standards. It was noted that *USP* Chapter 797 requires significant resources to implement. Council members questioned whether the increase in quality achieved through implementation of *USP* 797 is commensurate with the resources that are required. It was noted that the application of resources in other areas may have greater impact on patient outcomes. The Council believed ASHP should encourage analysis of the resource requirements (including manpower implications) when new standards are proposed by regulators and accrediting bodies.

Pharmacy managers are constantly challenged to prioritize the available resources to achieve medication-use standards. Specific demands vary by organization. Directors need assistance in deciding where to apply limited resources to achieve the greatest impact on patient care. Council members were complimentary of ASHP's many tools and resources to assist pharmacy directors with implementation of standards. The Council suggested a variety of specific ideas for tools and resources to assist pharmacy managers in implementing standards.

**Bar-Code Verification upon Compounding and Dispensing.** The Council discussed ASHP policies related to the use of bar-code verification in the medication-use process. Current ASHP policy advocates the use of machine-readable coding prior to administration of medications but does not address the use of machine-readable coding in the preparation and dispensing process. There is evidence that the use of bar-code-enabled machine-readable coding can reduce dispensing and medication errors. The Council discussed various potential applications of machine-readable coding within the medication use process, including inventory control, managing recalls, compounding intravenous admixtures, and dispensing medications.

The Council believed that the Section of Pharmacy Informatics and Technology would be the most knowledgeable about the specific applications of machine-readable coding and suggested that the Section review this matter and develop a policy proposal for review by the Board of Directors and the House of Delegates.

**Credentialing Vendors.** The Council discussed the changing nature of credentialing health care industry representatives (HCIRs) in hospitals and health systems. The Association of periOperative

Registered Nurses and the American College of Surgeons have developed policy statements on this topic. The Joint Commission's proposed 2009 standard LD.3.40 requires hospitals to provide information regarding quality and safety to staff, independent licensed practitioners, patients, families, and external interested parties. Concerns about patient confidentiality, the Health Insurance Portability and Accountability Act (HIPAA), HCIR access to patient care areas, and infection control requirements are among the factors that have led to increased interest in credentialing HCIRs.

A number of companies offering credentialing services have emerged in the marketplace, including RepTrax, StatusBlue, Vendor Clear, and Vendor Mate. These companies charge fees of \$100 to \$700, which are generally paid by HCIRs or their employers. The companies' services include compiling data about HCIRs, verifying credentials, and conducting criminal background checks on HCIRs and financial background checks on vendor companies. As individual institutions contract with credentialing companies, HCIRs must complete the credentialing process through multiple companies with varying requirements. These include proof of liability insurance, verification of training, vaccination or immunization records, criminal background checks, code of conduct training, proof of HIPAA training, and fingerprinting. In some cases these requirements do not distinguish between HCIRs whose role involves support in medical procedure areas and those who only meet with buyers or other staff outside patient care areas. These new requirements are often hospitalwide and are altering the role of pharmacists in managing vendor representatives.

The Council reviewed the ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Health Care Systems. The current guidelines were written in 1993 and were last reviewed in 1998. The guidelines focus on sales representatives of pharmaceutical companies, but today pharmacists interact with an array of vendors, including various computer, technology, and equipment vendors. The Council believed the guidelines should be updated to reflect the changing environment in which the pharmacy department interacts with various vendors. The Council also encouraged ASHP to investigate opportunities to collaborate with others to establish more uniform requirements for vendor credentialing.

**ASHP Guidelines on Managing Drug Product Shortages.** The Board also approved revisions to the ASHP Guidelines on Managing Drug Product Shortages that were recommended by the Council.



# House of Delegates Session—2009

## Board of Directors Report on the Council on Pharmacy Practice

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

Sheila A. Mitchell, Board Liaison

### Council Members

Edward M. Jai, Chair (California)  
Stephen F. Eckel, Vice-Chair (North Carolina)  
Jennifer Chan, Student (Illinois)  
Curtis D. Collins (Michigan)  
Kristina R. De Los Santos (Arizona)  
Lori J. Golterman (Washington, DC)  
Roy K. Guharoy (Massachusetts)  
James M. Hoffman (Tennessee)  
Kathleen A. Rottman, New Practitioner (Florida)  
Deborah R. Saine (Virginia)  
Jamie S. Sinclair (Minnesota)  
Jeffrey T. Thiel (Illinois)  
Bona E. Benjamin, Secretary

### Policy Recommendations

#### A. Pharmacist's Role in Providing Care for an Aging Population

- 1 To encourage expansion of geriatric health care services;
- 2 further,
- 3 To foster expanded roles for pharmacists in caring for
- 4 geriatric patients; further,
- 5 To support successful innovative models of team-based
- 6 geriatric care; further,
- 7 To encourage expansion of the number of ASHP-accred-
- 8 ited geriatric pharmacy residency programs.

#### Background

The Council believed and the Board agreed that the 2008 report from the Institute of Medicine (IOM), *Retooling for an Aging America: Building the Health Care Workforce*, which predicts a pending crisis caused by an inadequate workforce for a rapidly increasing elderly patient population, highlights issues significant for pharmacy. According to the report, older adults make up only about 12% of the U.S. population, but they account for approximately 26% of all physician office visits, 35% of all hospital stays, 34% of all prescriptions, 38% of all emergency medical service responses, and 90% of all nursing-home use. By 2030, the number of adults age 65 and older will have doubled to 70 million, or 20% of the total population, which will place even more demands on an already undermanned workforce.

The report recommends three major immediate actions to retool the workforce: enhancing the competence of all individuals in geriatric care, increasing the recruitment and retention of geriatric special-

ists and caregivers, and redesigning models of care, with broadened provider and patient roles to achieve greater flexibility.

The report discusses the significant role of pharmacists in counseling, monitoring of medication-related problems, and support of medication adherence. The pharmacist role on patient care teams and in medication therapy management becomes more important with the increasing numbers of frail or chronically ill patients treated with medication.

Many elderly people have a number of drug-related issues as well as cognitive impairment and complex needs. These factors increase the amount of expertise, time, and attention required to deliver appropriate care, which has implications for staffing. In addition, pharmacists may not have received sufficient training to assume this role. While professional education provides basic competence for medication management in the elderly, there are comparatively few geriatric pharmacy specialists. Professional education for pharmacists in geriatrics may vary widely, and only 10 programs offer ASHP-accredited geriatric pharmacy residency training.

The Council noted that ASHP does not have guidance that specifically addresses pharmacy services for geriatric patients, other than the ASHP Statement on the Pharmacist's Role in Primary Care, developed in 1999. The Council recommended placing high priority on the ASHP Guidelines on Geriatric Pharmaceutical Services currently in development.

#### B. Pharmaceutical Waste

- 1 To collaborate with regulatory bodies and appropriate
- 2 organizations to develop standards for the disposal of
- 3 pharmaceutical hazardous waste as defined in the Re-
- 4 source Conservation and Recovery Act (RCRA), for the
- 5 purpose of simplifying the disposal of these substances
- 6 by health systems; further,

- 7 To encourage pharmaceutical manufacturers and the  
 8 Environmental Protection Agency (EPA) to provide guid-  
 9 ance and assistance to hospitals and health systems in  
 10 pharmaceutical waste destruction and recycling efforts;  
 11 further,
- 12 To advocate that EPA update the list of hazardous sub-  
 13 stances under RCRA and establish a process for maintain-  
 14 ing a current list; further,
- 15 To urge federal, state, and local governments to har-  
 16 monize regulations regarding disposal of hazardous  
 17 pharmaceutical waste; further,
- 18 To advocate that the Food and Drug Administration  
 19 standardize labeling of drug products with information  
 20 relating to appropriate disposal; further,
- 21 To promote awareness within hospitals and health sys-  
 22 tems of pharmaceutical waste regulations; further,
- 23 To encourage research on the environmental and public  
 24 health impacts of drug products and metabolites excreted  
 25 in human waste; further,
- 26 To encourage pharmaceutical manufacturers to streamline  
 27 packaging of drug products to reduce waste materials.

(Note: This policy would supersede ASHP policy 0231.)

**Background**

The Council voted to revise ASHP policy 0231 as follows (under-  
 score indicates new text; ~~strike through~~ indicates deletions):

To collaborate ~~work~~ closely with regulatory bodies and appropriate organizations to develop standards for the disposal of that address pharmaceutical hazardous waste as defined in the Resource Conservation and Recovery Act (RCRA), for the purpose of simplifying the disposal of these substances by ~~in~~ health systems; further,

To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to health systems in ~~their~~ pharmaceutical waste-destruction and ~~waste~~-recycling efforts; further,

To advocate that EPA update the list of hazardous substances under RCRA and establish a process for maintaining a current list; further,

To urge federal, state, and local governments to harmonize regulations regarding disposal of hazardous pharmaceutical waste; further,

To advocate that the Food and Drug Administration standardize labeling of drug products with information relating to appropriate disposal; further,

To promote awareness within hospitals and health systems of pharmaceutical waste regulations ~~within health systems~~; further,

To encourage research on the environmental and public health impacts of drug products and metabolites excreted in human waste; further,

To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

The Council discussed how ASHP might help define pharmacists' responsibility to the public for safe disposal of hazardous pharmaceutical waste, outside their responsibility to be compliant with applicable regulations. The Council noted that current policy focuses on compliance with RCRA. A number of other issues that the revised ASHP policy should address include obsolete lists, variability in requirements, labeling, and research.

*Obsolete lists.* The waste stream is in part determined by the list to which a drug is assigned. However, these lists do not include all medications, especially newer products. If a drug is not listed, individual organizations either follow the method of disposal listed for similar drugs or drug classes or use no special disposal method at all. Minimally hazardous drugs are included on lists, creating needlessly burdensome disposal requirements.

*Variability in requirements.* Regulations vary from state to state and even from county to county. Large hospital systems are forced to create site-specific policies, which complicate communication and education about the appropriate management of waste.

*Labeling.* Ensuring that products for disposal are directed into the proper waste stream is left up to health care organizations. Many apply auxiliary labeling on-site to communicate this information. It would be more logical and efficient for the manufacturer to include this information in product labeling. The Council recommended that labeling immediate containers with disposal directions would ensure that this information reached the end user of the product. An example of how this might be done is the method used by the National Fire Protection Agency, which identifies hazards with specific symbols.

*Research.* Little research or guidance is available on the environmental effect of hazardous metabolites excreted in human waste. The Council believed more research is needed in this area.

**C. Automatic Stop Orders**

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

**Background**

The Council reviewed current policy on limiting duration of therapy contained in the ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control. It also reviewed the Centers for Medicare & Medicaid Services (CMS) Hospital Conditions of Participation requirement that hospitals assign automatic stop dates to orders if not specified by the prescriber, which reads:

A-0257 482.25(b)(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

Council members noted that automatic discontinuation of all medication orders with no clinical justification is problematic and has caused omitted doses and interruption of treatment. The CMS regulation does not specify what duration is appropriate, and some states have taken the requirement one step further and imposed specific durations in state regulations. The CMS regulation is outdated in light of The Joint Commission requirement for medication reconciliation and review of orders by a pharmacist.

After being informed that the ASHP Technical Assistance Bulletin on Drug Distribution and Control is slated for revision, the Council recommended that the revision should reflect the risks inherent in automatic cancellation of all medication orders and that the document should include recommendations for protecting patients from indefinite, open-ended medication orders. The Council expressed its support, with appropriate changes in federal statutes and regula-

tions, for drug-, class-, or indication-specific automatic stop-order policies based on monitoring requirements or other organizational policies.

**D. ASHP Statement on the Pharmacist’s Role in Antimicrobial Stewardship and Infection Prevention and Control**

- 1 To approve the ASHP Statement on the Pharmacist’s Role
- 2 in Antimicrobial Stewardship and Infection Prevention
- 3 and Control (Appendix A).

(Note: This statement would supersede the ASHP Statement on the Pharmacist’s Role in Infection Control, dated June 3, 1998.)

**Background**

The Council and Board requested that the ASHP Statement on the Pharmacist’s Role in Infection Control be updated to reflect more current thinking on antimicrobial stewardship and infection prevention and control, as reflected in the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship, which ASHP has endorsed.

**E. ASHP Statement on the Health-System Pharmacist’s Role in National Health Care Quality Initiatives**

- 1 To approve the ASHP Statement on the Health-System
- 2 Pharmacist’s Role in National Health Care Quality Initia-
- 3 tives (Appendix B).

**Background**

The Council and the Board voted to develop an ASHP statement that provides recommendations on how pharmacists can integrate leadership on quality initiatives into their day-to-day practice. The Council and the Board agreed that there are unique opportunities for pharmacists to contribute more of their professional resources to quality measure development; data collection, analysis, and dissemination; and development, implementation, and evaluation of evidence-based practices. The Council and the Board believed that pharmacists could be more involved in hospital and health-system efforts aimed at achieving and exceeding national quality indicators, including those indicators that directly address medication use. The Council and Board suggested that pharmacy departments should integrate health-system quality improvement initiatives into their strategic plans and that health-system administrators need to become more knowledgeable about the roles pharmacists can play in improving quality.

**Board Actions**

**Ethical Issues Associated with Pharmacist Dispensing of an Intermediate Category of Drugs.** The Council recommended and the Board did not support seeking revision of the *Code of Ethics for Pharmacists* to address potential conflicts of interest that might arise from dispensing medications under an intermediate category model. Board members commented that this action may be premature and should be deferred until pharmacist dispensing of the intermediate drug class is an established practice. However, the Board recommended that, when such a statement is developed collaboratively, a documentation system should be included as a key component. The Board suggested that the Council review this concept in the context of the ASHP Statement on Intermediate Drug Category at their next meeting.

**Resources on Pharmaceutical Waste Disposal for Pharmacists.** The Council recommended and the Board did not support development of a Web resource center on pharmaceutical waste disposal. The Board commented that the utility of such a resource is unknown, as pharmacists must consult applicable regulations at national, state, and local levels to ensure compliance. The Board also expressed concern that this project has the potential to be labor-intensive at a time when resources should be conserved for high-priority projects. Further, the Board noted that implementing the related proposed policy on pharmaceutical waste should be a priority.

**Pharmacist’s Role in Drug Safety.** The Council recommended and the Board voted

To develop resources for pharmacists on how to handle Food and Drug Administration (FDA) drug safety alerts, including a decision tool for interpreting alerts, determining the appropriate response, and communicating the appropriate actions to individuals or groups within the hospital or health system; further,

To provide educational programming on pharmacovigilance and pharmacoepidemiology that focuses on the pharmacist’s role in managing drug safety alerts, including evaluating, interpreting, and responding to alerts; further,

To provide regular updates to ASHP members on the progress of the FDA Sentinel Initiative, with analysis of implications for pharmacists, including effects on day-to-day practice.

The Council noted that managing FDA drug safety alerts presents a number of challenges and recommended that ASHP study the following implications for pharmacists: protecting the privacy of health information, developing standards and interface tools for interoperability, identifying and managing risk (Council members all reported that their organizations have difficulty interpreting the significance of many of the FDA alerts they currently receive), and the role of the individual pharmacist (the Council recommended that ASHP study and delineate the pharmacist’s role in drug safety by monitoring and analyzing developments in the implementation of the Sentinel System). The Council suggested that the Section of Clinical Specialists and Scientists be consulted for additional recommendations on interpretation of FDA alerts.

**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.)

- Pharmaceutical Counterfeiting (0401)
- Ready-to-Use Packaging for Ambulatory Patients (0402)
- Telepharmacy (9920)
- Pharmacist Validation of Information Related to Medications (9921)
- Role of Pharmacists and Business Leaders in Health Care Services and Policies (9819)
- Use of Color to Identify Drug Products (9608)
- Therapeutic Interchange (8708)
- International System of Units (8612)
- ASHP Position on Assisted Suicide (9915)
- Use of Drugs in Capital Punishment (8410)
- ASHP Statement on the Pharmacist’s Role in Clinical Pharmacokinetic Monitoring
- ASHP Statement on the Pharmacist’s Role in Substance Abuse Prevention, Education, and Assistance

- ASHP Statement on the Pharmacist's Role in the Care of Patients with HIV Infection
- ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness
- ASHP Statement on Pharmacist's Decision-making on Assisted Suicide
- ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records
- ASHP Guidelines on Pharmaceutical Services in Correctional Facilities. (The Council reaffirmed this document, and noted that it

has not been revised in 13 years. The Council recommended that it be reviewed by pharmacists who practice in prisons to ensure its currency and then be reconsidered in 2009 in light of results of the review.)

- ASHP Guidelines on the Pharmacist's Role in Immunization
- ASHP Guidelines on Pharmacy-Prepared Ophthalmic Products. (The Council reaffirmed this document while awaiting clarification of specific concerns expressed by the group revising the ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products.)

## Other Council Activity

### Pharmacist's Role in the Health Care (Medical) Home.

The Council voted to develop policy that fosters and supports the participation of the pharmacist in the health care (medical) home model and aligns with the policy on payment structure developed by the Council on Public Policy. The policy should also be consistent with the current ASHP Statement on the Pharmacist's Role in Primary Care, but avoid redundancy.

**Practice Models in Hospital and Health-System Pharmacy.** The Council was asked to provide insight and direction for ASHP's Pharmacy Practice Model Project. Council members agreed that there is not one universal ideal practice model. The Council recommended that members of the project steering committee first establish a vision for the practice model and then identify guiding principles, rather than defining a specific structure for the model. Once the model is developed, barriers and opportunities should also be analyzed by the steering committee. The guiding principles should be broad enough to be applicable to all organizations.

The Council proposed the following concepts that could be developed into guiding principles: patient-centeredness; continuous, 24-hour per day, 7-day per week care, as provided by physicians and nurses; broad expertise integrated with specialization, to ensure a consistent level of care; accountability for patient outcomes; and seamless care. The Council stressed the importance of agreed-upon definitions for the practice model concept (e.g., "clinical pharmacy") to avoid the lack of common vision and understanding that has impeded work on this issue, and they hoped that one of the questions addressed would be how best to integrate generalists, whose expertise has broad applicability, with highly trained specialists who see far fewer but more acutely ill patients. Council members cautioned that this issue requires careful thought if specialists will be expected to take on broader responsibilities. A new expectation will have to be set for postgraduate year 2 (PGY2) residencies; practitioners in these residencies consider their practice model to be defined by postgraduate training (e.g., a critical care residency). The Council also thought it was important to consider PGY2 residents' expectation for better hours and higher salaries consistent with or in light of their advanced training. The Council recommended considering how the practice model can avoid giving the impression that advanced training is not valued if clinical specialists work 24-7 and share generalist functions. The Council also believed that pharmacists who prefer or who are expert in distributive or dispensing roles need to be considered in the model as well. A well-run operation is important, and individuals in these roles allow others more time for research and publishing.

**ASHP Guidelines on Clinical Drug Research.** The Council discussed merging these guidelines with the ASHP Statement on Pharmaceutical Research in Organized Health Care Systems and updating the document, as it has not been revised since approval in 1997. An updated guideline would set a standard of practice that would assist practitioners in changing unrealistic and burdensome sponsor requirements, such as return of empty vials, paper distribu-

tion records, and other impediments to efficient handling of study drugs. The document should emphasize stronger pharmacy oversight for the entire process of investigational medication use, including application of decision support, the electronic record, safe conduct of clinical trials, and safe use of investigational drugs. The Council recommended that the appropriate section advisory group revise the guidelines.

**ASHP Guidelines on Surgery and Anesthesiology Pharmaceutical Services.** The Council considered a recommendation from the Council on Pharmacy Management to expand the guidelines to include perioperative areas. The "Purpose" section of that document states that the guidelines apply to any area where surgical or anesthesia procedures take place, and the Council believed that this includes perioperative areas. However, the Council noted that the guidelines have not been revised since 1997 and recommended review and updating to reflect contemporary practice.

**ASHP Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures.** The Council recommended that the ASHP Guidelines on the Safe Use of Automated Compounding Devices for the Preparation of Parenteral Nutrition Admixtures be retained. The American Society of Parenteral and Enteral Nutrition (ASPEN) has established guidance on compounders in its document *Safe Practices for Parenteral Nutrition*. The Council has the option of recommending that ASHP endorse this policy. The Council decided to compare ASPEN's document with ASHP's to ensure that ASHP's positions are adequately covered by ASPEN before a decision is made about recommending endorsement.

**Clinical Pharmacist's Role in the Emergency Department.** The Council considered a suggestion that ASHP develop guidelines on the clinical role of the emergency department pharmacist and deferred development of such guidelines to the Section of Clinical Specialists and Scientists Advisory Group on Emergency Medicine, which was instrumental in developing the ASHP Statement on Pharmacy Services to the Emergency Department.

**Use of the Terms "Transcribe" and "Transcribing."** After review of background material, Council members commented that they appreciate the issues raised by the Recommendation from the House of Delegates on this topic. The Council noted that there is a lack of common understanding of definitions of many terms associated with order entry and that a more appropriate term is needed to describe the evaluation, interpretation, and implementation of a medication order. The Council believed that the cognitive functions implied by the term "order perfection" are addressed in the definition of dispensing contained in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. The Council encouraged ASHP to avoid the use of the terms "transcribe" and "transcribing" when referring to the dispensing process.

**Council Review and Recommendations for Guidance Documents Currently in Development.** The Council voted to discontinue development of the following ASHP statements and guidelines:

- Statement on team-based care. (The Council agreed that this topic is addressed in other ASHP policy.)
- Statement on the pharmacist’s role in computerized prescriber order entry (CPOE). (The Council noted that ASHP guidelines on CPOE are currently in development.)
- Statement on telepharmacy patient–pharmacist relationship. (The Council agreed to discontinue the document but urged that guidance on pharmaceutical care via telepharmacy be included in the guidelines on remote order entry currently in development.)
- Guidelines on measuring preventable medication misadventures. (The Council urged that measurement and cost implications of preventable medication errors and the issue of intimidation and resultant process breakdowns be addressed in the revision of the ASHP Guidelines on Preventing Medication Errors in Hospitals.)
- ASHP Statement on Pharmaceutical Research in Organized Health Care Systems. (The Council agreed that this guidance should be

included in the previously recommended revision of the ASHP Guidelines on Clinical Drug Research.)

- ASHP Statement on Unit-Dose Drug Distribution. (The Council agreed that this statement should be combined into the ASHP Guidelines on Hospital Drug Distribution and Control currently under development.)

The Council believed there is merit in ongoing monitoring of documents in development for best practices, how best practices are being used, and how they could be used better. The Council voted to include this review as a standing agenda item, beginning in 2009.

**Update of Best Practices Indexing System.** The Council recommended the use of more contemporary keywords and a greater number of keywords for indexing *Best Practices for Hospital and Health-System Pharmacy*.

**Therapeutic Use of Alcohol.** The Council recommended that the Council on Therapeutics evaluate the use of alcohol as a medication and provide recommendations for an ASHP position statement.

**1 Appendix A—ASHP Statement on the Pharmacist’s  
2 Role in Antimicrobial Stewardship and Infection  
3 Prevention and Control**

**4 Position**

5 The American Society of Health-System Pharmacists (ASHP)  
6 believes that pharmacists have a responsibility to take prominent  
7 roles in antimicrobial stewardship programs and participate in the  
8 infection prevention and control programs of health systems. This  
9 responsibility arises, in part, from pharmacists’ understanding of and  
10 influence over antimicrobial use within the health system. Further,  
11 ASHP believes that the pharmacist’s ability to effectively participate  
12 in antimicrobial stewardship and infection prevention and control  
13 efforts can be realized through clinical endeavors focused on proper  
14 antimicrobial utilization and membership on multidisciplinary  
15 work groups and committees within the health system. These ef-  
16 forts should contribute to the appropriate use of antimicrobials,  
17 ultimately resulting in successful therapeutic outcomes for patients  
18 with infectious diseases, and reduce the risk of infections for other  
19 patients and health care workers.

**20 Background**

21 Antimicrobial stewardship is utilized in practice settings of health  
22 systems to improve patient outcomes while minimizing the unin-  
23 tended consequences of antimicrobial use. The goals of antimicrobial  
24 stewardship programs include attenuating or reversing antimicrobial  
25 resistance, preventing antimicrobial-related toxicity, and reducing  
26 the costs of inappropriate antimicrobial use and health care-  
27 associated infections. Guidelines published by the Infectious Dis-  
28 eases Society of America and the Society for Healthcare Epidemi-  
29 ology of America and endorsed by ASHP and other organizations  
30 describe an evidence-based approach to antimicrobial stewardship  
31 in health systems and the important role pharmacists with infec-  
32 tious diseases training have in leading stewardship efforts.<sup>1</sup>

33 Identifying and reducing the risks of developing, acquiring, and  
34 transmitting infections among patients, health care workers, and  
35 others is an important part of improving patient outcomes. In  
36 order to maximize outcomes, antimicrobial stewardship should  
37 be used in combination with infection prevention and control  
38 practices.<sup>1</sup> Most health systems maintain an infection prevention  
39 and control program directed by a multidisciplinary committee.  
40 The specific program and responsibilities of the infection preven-  
41 tion and control committee (or its equivalent) may differ among  
42 health systems.

Typically, the infection prevention and control committee devel- 43  
ops organizational policies and procedures addressing 44

1. The management and provision of patient care and employee 45  
health services regarding infection or infection prevention and 46  
control. 47
2. The education of staff, patients, family members, and other care- 48  
givers in the prevention and control of infections. 49
3. Surveillance systems to track the occurrence and transmission of 50  
infections. 51
4. Surveillance systems to track the use of antimicrobials and the 52  
development of antimicrobial resistance. 53
5. Promotion of evidence-based practices and interventions to 54  
prevent the development of infections. 55

**Responsibilities of Pharmacists** 56

Pharmacists’ responsibilities for antimicrobial stewardship and 57  
infection prevention and control include promoting the optimal use 58  
of antimicrobial agents, reducing the transmission of infections, and 59  
educating health professionals, patients, and the public. 60

**Promoting optimal use of antimicrobial agents.** An 61  
important clinical responsibility of the pharmacist is to ensure the 62  
optimal use of antimicrobial agents throughout the health system. 63  
Functions related to this responsibility may include 64

1. Encouraging multidisciplinary collaboration within the health 65  
system to ensure that the prophylactic, empirical, and therapeutic 66  
uses of antimicrobial agents result in optimal patient outcomes. 67  
These activities may include antimicrobial-related patient care 68  
(e.g., aiding in appropriate selection, optimal dosing, rapid initia- 69  
tion, and proper monitoring and de-escalation of antimicrobial 70  
therapies) as well as the development of restricted antimicrobial- 71  
use procedures, therapeutic interchange, treatment guidelines, 72  
and clinical care plans.<sup>2</sup> 73
2. Working within the pharmacy and therapeutics committee (or 74  
equivalent) structure, which may include infectious disease- 75  
related subcommittees, to ensure that the number and types of 76  
antimicrobial agents available are appropriate for the patient 77  
population served. Such decisions should be based on the needs 78  
of special patient populations and microbiological trends within 79  
the health system. High priority should be given to developing 80  
antimicrobial-use policies that result in optimal therapeutic out- 81  
comes while minimizing the risk of the emergence of resistant 82  
strains of microorganisms. 83
3. Operating a multidisciplinary, concurrent antimicrobial steward- 84  
ship program that uses patient outcomes to assess the effectiveness 85  
of antimicrobial-use policies throughout the health system. 86

- 1 4. Generating and analyzing quantitative data on antimicrobial drug  
2 use to perform clinical and economic outcome analyses.
- 3 5. Working with the microbiology laboratory personnel to ensure  
4 that appropriate microbial susceptibility tests are reported on  
5 individual patients in a timely manner, and collaborating with  
6 the laboratory, infectious diseases specialists, and infection pre-  
7 ventionists in compiling susceptibility reports (at least annually)  
8 for distribution to prescribers within the health system to guide  
9 empirical therapy.
- 10 6. Utilizing information technology to enhance antimicrobial stew-  
11 ardsnip through surveillance, utilization and outcome reporting,  
12 and the development of clinical decision support tools.
- 13 7. Facilitating safe medication management practices for antimicro-  
14 bial agents by utilizing efficient and effective systems to reduce  
15 potential errors and adverse drug events.

16 **Reducing the transmission of infections.** Pharmacists  
17 should participate in efforts to prevent or reduce the transmission  
18 of infections among patients, health care workers, and others within  
19 all of the health system's applicable practice settings. This may be  
20 accomplished through

- 21 1. Participating in the infection prevention and control committee  
22 (or its equivalent).
- 23 2. Establishing internal pharmacy policies, procedures, and quality  
24 control programs to prevent contamination of drug products  
25 prepared in or dispensed by the pharmacy department. This is  
26 of paramount importance in the preparation and handling of  
27 sterile products.<sup>3</sup> Other considerations include (but are not lim-  
28 ited to) provisions for cleaning pharmaceutical equipment (e.g.,  
29 laminar-airflow hoods and bulk-compounding equipment) and  
30 establishment of appropriate personnel policies (e.g., limiting  
31 the activities of staff members who exhibit symptoms of a viral  
32 respiratory illness or other infectious condition).
- 33 3. Encouraging the use of single-dose packages of sterile drug  
34 products rather than multiple-dose containers, except in sterile  
35 environments.
- 36 4. Recommending proper labeling, dating, and storage of sterile  
37 products and multiple-dose sterile-product containers (if used).
- 38 5. Encouraging routine immunization (e.g., influenza vaccination)  
39 of hospital staff and others who impact the patient care environ-  
40 ment, and promoting periodic screening for selected transmissible  
41 diseases (e.g., tuberculosis) in accordance with health-system  
42 policy and federal, state, or local regulations.
- 43 6. Promoting adherence to standard precautions by health care  
44 workers, patients, and others who impact the patient care  
45 environment.<sup>4</sup>
- 46 7. Collaborating in the development of guidelines for risk assess-  
47 ment, treatment, and monitoring of patients and health care  
48 workers who have been in contact with persons with a transmis-  
49 sible infectious disease.
- 50 8. Striving for zero tolerance of health care-associated infections,  
51 including surgical site infections, catheter-associated bloodstream  
52 infections, catheter-associated urinary tract infections, and  
53 ventilator-associated pneumonia.

54 **Educational activities.** The pharmacist's role includes provid-  
55 ing education and information about antimicrobial stewardship and  
56 infection prevention and control to health professionals, patients,  
57 and members of the public who come in contact with the health  
58 system's practice settings. Incorporating active intervention tech-  
59 niques, such as formulary restriction and preauthorization, enhance  
60 the effectiveness of educational activities in the patient care setting.<sup>1</sup>  
61 Specific activities may include

- 62 1. Providing clinical conferences, newsletters, and other types  
63 of educational forums for health professionals on topics such  
64 as antimicrobial use and resistance, decontaminating agents  
65 (disinfectants, antiseptics, and sterilants), aseptic technique and  
66 procedures, and sterilization methods.
- 67 2. Educating and counseling inpatients, ambulatory care patients,  
68 home care patients, and their families and caregivers in the fol-  
69 lowing areas: adherence to prescribed directions for antimicrobial  
70 use, storage and handling of medications and administration  
71 devices, and other infection prevention and control procedures  
72 (e.g., medical waste disposal).

3. Participating in public health education and awareness programs  
aimed at controlling the spread of infectious diseases by:
  - a. Promoting prudent use of antimicrobials, 75
  - b. Providing immunization access for children and adults, and 76
  - c. Promoting appropriate infection prevention and control 77  
measures (e.g., proper hand hygiene techniques). 78
4. Providing exposure to antimicrobial stewardship and infection 79  
prevention and control practices through experiential and didac- 80  
tic training for practicing health-system pharmacists, students, 81  
residents, and research fellows. 82

**Education and Training of Pharmacists** 83

ASHP recognizes that the current shortage of pharmacists with  
advanced training in infectious diseases and the limited number of  
training opportunities may require pharmacists without such training  
to assume some of the responsibilities described above. ASHP supports  
the expansion of pharmacy education and postgraduate residency  
training on infectious diseases in order to develop an adequate supply  
of pharmacists trained to deliver these essential services. 90

**Conclusion** 91

ASHP believes that pharmacists have a responsibility to take  
prominent roles in antimicrobial stewardship and infection preven-  
tion and control programs in health systems. Pharmacists should  
participate in antimicrobial stewardship and infection prevention  
and control efforts through clinical endeavors focused on proper an-  
timicrobial utilization and membership on relevant multidisciplinary  
work groups and committees within the health system. 98

**References** 99

1. Dellit TH, Owens RC, McGowan JE, et al. Infectious Diseases Society of America and  
the Society for Healthcare Epidemiology of America Guidelines for Developing an  
Institutional Program to Enhance Antimicrobial Stewardship. *Clin Infect Dis*. 2007;  
44:159-77. 100-103
2. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacist's  
role in the development, implementation, and assessment of critical pathways. *Am J  
Health-Syst Pharm*. 2004; 61:939-45. 104-106
3. American Society of Health-System Pharmacists. ASHP guidelines on quality assurance  
for pharmacy-prepared sterile products. *Am J Health-Syst Pharm*. 2000; 57:1150-69. 107-108
4. Siegel JD, Rhinehart E, Jackson M, et al. 2007 Guideline for Isolation Precautions:  
Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007. Available  
at: <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf> (accessed  
February 18, 2009). 109-112

**Suggested Readings** 113

Centers for Disease Control and Prevention. Guideline for disinfection and sterilization  
in healthcare facilities, 2008. Accessed 15 December 2008. [http://www.cdc.gov/ncidod/dhqp/  
pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf) 114-116

Centers for Disease Control and Prevention [CDC]. Guidelines for environmental infec-  
tion control in health-care facilities: recommendations of CDC and the Healthcare Infection  
Control Practices Advisory Committee (HICPAC). *MMWR*. 2003; 52 (No. RR-10): 1-48. 117-119

Diekema DJ, Doebbeling BN. Employee health and infection control. *Infect Control Hosp  
Epidemiol*. 1995; 16:292-301. 120-121

Gardner P, Schaffner W. Immunization of adults. *N Engl J Med*. 1993; 328:1252-8. 122

Goldmann DA, Weinstein RA, Wenzel RP, et al. Strategies to prevent and control the  
emergence and spread of antimicrobial-resistant microorganisms in hospitals. A challenge  
to hospital leadership. *JAMA*. 1996; 275:234-40. 123-124

Kollef M, Shapiro S, Fraser V, et al. A randomized trial of ventilator circuit changes. *Ann  
Intern Med*. 1995; 123:168-74. 125-126

MacDougall C, Polk RE. Antimicrobial stewardship programs in health care systems. *Clin  
Microbiol Rev*. 2005 Oct; 18(4):638-56. 127-129

Shlaes DM, Gerding DN, John JF Jr, et al. SHEA and IDSA Joint Committee on the  
Prevention of Antimicrobial Resistance: guidelines for the prevention of antimicrobial  
resistance in hospitals. *Clin Infect Dis*. 1997; 25:584-99. 130-132

Sepkowitz KA. Occupationally acquired infections in health care workers. *Ann Intern  
Med*. 1996; 125:826-34, 917-28. 133-134

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**1 Appendix B—ASHP Statement on the Health-  
2 System Pharmacist’s Role in National Health Care  
3 Quality Initiatives**

**4 Position**

5 The American Society of Health-System Pharmacists (ASHP) be-  
6 lieves that pharmacists who practice in hospitals and health systems  
7 (“health-system pharmacists”) have a critical leadership role in  
8 national health care quality improvement initiatives. Health-system  
9 pharmacists possess the knowledge of drug therapy and medication-  
10 use systems required to successfully implement quality assurance  
11 and improvement programs. These pharmacists should use their  
12 authority over and accountability for medication management sys-  
13 tems to align medication use in hospitals and health systems with  
14 the national health care quality agenda.

**15 Background**

16 Major reports from the Institute of Medicine (IOM) have demon-  
17 strated that the quality and safety environment across the health  
18 care industry needs significant transformation. *The Urgent Need to*  
19 *Improve Health Care Quality* suggested that the quality of the health  
20 care system in the United States could be accurately measured and  
21 that the quality of care was being compromised by the underuse,  
22 overuse, and misuse of health care entities.<sup>1</sup> *Crossing the Quality*  
23 *Chasm* built a compelling case that the American health care delivery  
24 system requires major restructuring and proposed goals for improv-  
25 ing six key dimensions of health care quality: safety, timeliness, ef-  
26 fectiveness, efficiency, equity, and patient-centeredness (the “STEEP”  
27 framework).<sup>2</sup> To achieve these aims, IOM called for fundamental  
28 reforms, including new payment methodologies, public reporting,  
29 and transparency of quality improvement data.

30 Since the release of these reports, health care policymakers, pro-  
31 viders, purchasers, payers, consumers, and others have responded  
32 in ways that are beginning to change the U.S. health care delivery  
33 system. These changes are influenced by a growing number of private  
34 and public organizations, including The Joint Commission, Centers  
35 for Medicare and Medicaid Services (CMS), National Quality Forum,  
36 National Priorities Partnership, Agency for Healthcare Research  
37 and Quality, Institute for Healthcare Improvement, and American  
38 Health Quality Association, among others. These organizations,  
39 alone or in collaboration, identify health care quality measures to  
40 set the national health care quality agenda. These quality measures  
41 are collected and reported through both mandatory and voluntary  
42 reporting systems, and the outcome measurements of a health  
43 system may be linked to reimbursement (e.g., through CMS pay-  
44 for-performance programs).

**45 Responsibilities of Health-System Pharmacists**

46 Many national health care quality measures are related to medi-  
47 cation use.<sup>3</sup> Health-system pharmacists are strategically positioned  
48 to integrate practices and procedures that support these quality  
49 measures into the medication-use system. To help align medication  
50 use in hospitals and health systems with the national health care  
51 quality agenda, health-system pharmacists should

- 52 • Become familiar with the organizations that influence the national
- 53 health care quality agenda and monitor those organizations for
- 54 changes in medication-use-related quality measures.

- Participate in the development, implementation, and evaluation 55  
of national and state health care quality improvement initiatives 56  
related to medication use. 57
- Collaborate with other health care professionals to evaluate 58  
medication-use practices in their organizations and develop and 59  
implement programs that optimize patient outcomes, improve 60  
medication use, and align with the national health care quality 61  
agenda, including expanding the scope and reach of pharmacists’ 62  
services when appropriate. 63
- Collect, analyze, and report data that measure health care quality 64  
related to medication use, and support the public availability of 65  
those data. 66
- Integrate and align information systems in their organizations 67  
with the national health care quality agenda. 68
- Educate other health care practitioners, health care executives, 69  
and the public about medication-related health care quality 70  
improvement initiatives and the critical role pharmacists have 71  
in those initiatives (e.g., by publishing articles about innovative 72  
pharmacy services that improve patient outcomes or medication 73  
use). 74
- Encourage national pharmacy organizations to support, guide, 75  
and provide education related to the national health care quality 76  
agenda. 77

**Conclusion**

78 The number of mandatory and voluntary health care quality 79  
measures related to the use of medications is large and growing. 80  
As medication-use experts, health-system pharmacists have a re- 81  
sponsibility to become knowledgeable about national health care 82  
quality improvement initiatives and to align their practices accord- 83  
ingly. Because health-system pharmacists possess knowledge of drug 84  
therapy and medication-use systems and have authority over and 85  
accountability for medication management systems, they have a 86  
fundamental leadership role in the development, implementation, 87  
and evaluation of health care quality improvement initiatives. 88

**References**

89  
90 1. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of  
91 Medicine National Roundtable on Health Care Quality. *JAMA*. 1998; 280:1000-5.  
92 2. Institute of Medicine Committee on Quality of Health Care in America. *Crossing the*  
93 *quality chasm: a new health system for the 21st century*. Washington, DC: National  
94 Academy Press; 2001: 43-56.  
95 3. Bohenek WS, Grossbart SR. Pharmacists’ role in improving quality of care. *Am J Health*  
96 *Syst Pharm*. 2008; 65:1566-70.

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# House of Delegates Session—2009

## 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.

Stanley S. Kent, Board Liaison

### Council Members

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Jillian James Foster, Vice-Chair (Mississippi)  
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Donna S. Wall (Indiana)  
Brian M. Meyer, Secretary

### Policy Recommendations

#### A. Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Drug Therapy Management

1 To advocate expansion of collaborative drug therapy  
2 management (CDTM) practices in which the prescriber  
3 and the licensed pharmacist agree upon the conditions  
4 under which the pharmacist monitors and adjusts a  
5 patient's drug therapy; further,

6 To acknowledge that as a step toward the goal of univer-  
7 sal recognition of and payment for pharmacist CDTM  
8 services, public or private third-party payers may require  
9 licensed pharmacists to demonstrate their competence  
10 to provide CDTM, before the payers authorize them to  
11 engage in or be paid for such clinical services; further,

12 To support (1) the development (as a professional  
13 initiative by pharmacist associations rather than as a  
14 government activity) of national standards for deter-  
15 mining a pharmacist's competence to provide CDTM  
16 and (2) the appropriate use of these standards by clini-  
17 cal privileging systems, government authorities, and  
18 public or third-party payers; further,

19 To support the use of clinical privileging by hospitals  
20 and health systems to assess a licensed pharmacist's  
21 competence to engage in CDTM within the hospital or  
22 health system; further,

23 To advocate that state boards of pharmacy apply the  
24 principles of continuous quality improvement in assess-  
25 ing the quality, safety, and outcomes of CDTM.

26 (Note: *Privileging* is the process by which an oversight  
27 body of a health care organization or other appropriate  
28 provider body, having reviewed an individual health care  
29 provider's credentials and performance and found them  
30 satisfactory, authorizes that individual to perform a spe-  
31 cific scope of patient care services within that setting.)

(Note: This policy would supersede ASHP policy 0318.)

#### Background

The Council voted to recommend completely revising policy 0318. For ease of comparison, policy 0318 reads as follows:

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

To support the current practice of pharmacists and prescribers negotiating and establishing collaborative drug therapy management agreements in which the pharmacist receives delegated authority; further,

To support the use of privileging processes in those practice environments where explicit privileging is required to receive delegated authority; any additional training or credentials required of pharmacists engaging in these practices should be determined by the local practice site; further,

To stipulate that privileging should be conducted by an oversight body of the practice site.

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

The Council revised policy 0318 in response to a New Business item passed by the House of Delegates in June 2008. The New Business item noted the need to revise policy 0318 in order to provide more flexibility for ASHP to achieve its goal of attaining recognition of pharmacist collaborative drug therapy management (CDTM) services by Medicare. Over 45 states have enacted CDTM. In addition, federal legislation (H.R. 5780) was introduced that would allow for Medicare payment for CDTM for pharmacists that are designated by state law as a "clinical pharmacist practitioner" or "pharmacist clinician" (currently North Carolina and New Mexico, respectively). These two designations are conferred upon licensed pharmacists who also complete physical assessment training and experiential hours. Since policy 0318 was explicit in stating that licensure was the only state requirement, ASHP was unable to support H.R. 5780.

The Council determined that a new policy would best serve this purpose while maintaining certain elements of policy 0318. In developing the newly proposed policy, the Council recognized and the Board concurred that licensure may not be the only state-imposed legal requirement to provide CDTM. The proposed policy not only supports CDTM but advocates for its expansion. It continues to support and apply the clinical privileging process to CDTM as practiced within hospitals and health systems. Also, it recognizes that payers may require pharmacists to demonstrate competence to provide CDTM as a step toward universal recognition of pharmacist-provided CDTM. Finally, it supports a professional initiative to develop national standards for determining pharmacist competence and the appropriate use of these standards by clinical privileging systems, governments, and public or third-party payers.

The Council acknowledged that proposals similar to H.R. 5780 would serve to move the profession forward in its goal of recognizing and paying pharmacists for CDTM services. In developing the proposed policy, the Council and Board wanted to enable ASHP to support these proposals as a step toward universal recognition of pharmacists as providers. The Council and Board acknowledged that this initial step would demonstrate to payers and the public that pharmacists providing these services have attained a required level of competence. In addition, the Council and Board noted the need for the profession itself to develop national standards for credentials that are used to determine a pharmacist's competence to provide CDTM. Council and Board members also noted the need for state boards of pharmacy to establish quality improvement processes with respect to patient safety and outcomes of CDTM services.

**B. Approval of Follow-on Biological Medications**

- 1 To encourage the development of safe and effective
- 2 follow-on biological medications in order to make such
- 3 medications more affordable and accessible; further,
  
- 4 To encourage research on the safety, effectiveness, and
- 5 interchangeability of follow-on biological medications;
- 6 further,
  
- 7 To support legislation and regulation to allow Food and
- 8 Drug Administration approval of follow-on biological
- 9 medications; further,
  
- 10 To require postmarketing surveillance for all follow-on
- 11 biological medications to ensure their continued safety,

- 12 effectiveness, purity, quality, identity, and strength;
- 13 further,

- 14 To advocate for adequate reimbursement for biological
- 15 medications that are deemed interchangeable; further,

- 16 To promote education of pharmacists about follow-on
- 17 biological medications and their appropriate use within
- 18 hospitals and health systems.

- 19 (Note: Follow-on biological medications are also referred
- 20 to as biosimilars, follow-on protein products, biogenerics,
- 21 comparable biologicals, and generic biopharmaceuticals.)

(Note: This policy would supersede ASHP policy 0519.)

**Background**

The Council voted to recommend amending policy 0519 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To encourage the development of safe and effective follow-on biological generic versions of biologic medications in order to make such medications more affordable and accessible; further,

To encourage research on ~~scientific methods to ensure~~ the safety, effectiveness, and interchangeability therapeutic equivalence of follow-on biological generic biologic medications; further,

To support legislation and regulation to allow Food and Drug Administration approval of follow-on biological generic versions of biologic medications; ~~;~~ further,

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

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

To promote education of pharmacists about follow-on biological medications and their appropriate use within hospitals and health systems.

(Note: Follow-on biological medications are also referred to as biosimilars, follow-on protein products, biogenerics, comparable biologicals, and generic biopharmaceuticals.)

There has been renewed interest in legislative proposals to establish a regulatory pathway for these medications. In response, the Council made changes to the existing policy by using a standard term, "follow-on biological medications," and parenthetically referring to other terms used to describe biological products that are in need of a regulatory pathway in order to be marketed. The Council also replaced the term "therapeutic equivalence" with "interchangeability," since that is a term that will be considered in legislative proposals to establish a regulatory pathway for these medications. The Council also added three new clauses at the end of the policy. The Council and Board believed that a requirement for postmarketing surveillance to ensure patient safety as well as product effectiveness is an important component of a regulatory pathway. The Council and Board also noted that reimbursement for follow-on biological medications deemed interchangeable should be adequate in order to positively affect patient access. The Council and Board noted the continuing need for pharmacist education about follow-on biological medications and their appropriate use within hospitals and health systems. This is particularly important as a regulatory pathway is established and follow-on biological medications are approved for marketing.

**C. Pharmaceutical Product and Supply Chain Integrity**

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

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

17 To advocate the establishment of meaningful penalties  
 18 for companies that violate current good manufactur-  
 19 ing practices (cGMPs) intended to ensure the quality,  
 20 identity, strength, and purity of their marketed drug  
 21 product(s) and raw materials; further,

22 To urge Congress and state legislatures to provide ad-  
 23 equate funding, or authority to impose user fees, to  
 24 accomplish these objectives.

(Note: This policy would supersede ASHP policy 0722.)

**Background**

The Council voted to recommend amending policy 0722 as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

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

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

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

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

The Council’s discussion of the need for additional authority and stronger enforcement by FDA addressed a delegate Recommendation concerning the recent contamination of heparin products manufactured with raw materials from China. The Council revised

policy 0722 to emphasize the need for FDA resources and authority to enforce adherence to cGMPs by all suppliers in the supply chain. The Council and Board noted that since foreign facilities are notified of most FDA inspections in advance, they have little incentive to maintain cGMPs. The Council and Board believed that holding the manufacturer of the finished product responsible for the compliance of all its suppliers would provide that incentive. To further enhance enforcement, the Council and Board believed that meaningful penalties for violations of cGMPs should be available to FDA. Finally, the Council and Board believed that to ensure supply chain integrity, the manufacturer should maintain ongoing surveillance of its products as well as its manufacturing processes.

**D. Pharmacist Role in the Health Care (Medical) Home**

1 To advocate to health policymakers, payers, and other  
 2 stakeholders for the inclusion of pharmacists as a care  
 3 provider within the health care (medical) home model;  
 4 further,

5 To ensure that there are appropriate reimbursement  
 6 mechanisms for the care that pharmacists provide (in-  
 7 cluding care coordination services) within the health  
 8 care home model; further,

9 To advocate to the Centers for Medicare & Medicaid Ser-  
 10 vices (CMS) that pharmacists be included in demonstra-  
 11 tion projects for the health care home model; further,

12 To encourage comparative effectiveness research and  
 13 measurement of key outcomes (e.g., clinical, economic,  
 14 quality, access) for pharmacist services in the health care  
 15 home model.

**Background**

The Council voted to recommend policy addressing the emerging concept of a “health care home,” also referred to as a “medical home.” Medical home is the term developed and used by medical organizations and health care home is used by others including health policymakers. The model, first described by the American Academy of Pediatrics in 1992 and soon to be the subject of demonstration projects by the Centers for Medicare & Medicaid Services (CMS), emphasizes care coordination from a medical practice and uses an interdisciplinary health care team approach to managing a patient’s overall health. Council members noted the recent Medicare Payment Advisory Commission (MedPAC) report that discussed a health care home program in Medicare. The report stated that, ideally, medication reviews conducted by a health care home should be coordinated by a pharmacist. The Council also noted that CMS will begin health care (medical) home demonstration projects in 2009. The Council and Board believed it is important to advocate that a pharmacist be included in the health care (medical) home model and that pharmacists be factored into the compensation for services provided. The Council and Board also believed that research and measurement of key outcomes are important to include in any demonstration and permanent delivery model, in order to determine the effectiveness of the care that is delivered.

**E. Regulation of Interstate Pharmacy Practice**

1 To advocate that state governments, including legislatures  
 2 and boards of pharmacy, adopt laws and regulations that  
 3 harmonize the practice of pharmacy across state lines in  
 4 order to provide a consistent, transparent, safe, and ac-  
 5 countable framework for pharmacy practice.

**Background**

The Council reviewed existing policies (0716, 0507, 0523, 9813, 9205) dealing with automation, information technology, and

telepharmacy and their increasing application and implementation across state borders. Council and Board members believed that an overarching policy is needed to express the notion that state regulatory bodies need to work more closely together and provide a more consistent and transparent regulatory framework in order to achieve a high level of patient safety. It was noted that with the emergence of new technology, borders are becoming more artificial and coordination between states is needed. The Council and Board observed that through dialogue with the National Association of Boards of Pharmacy (NABP) and individual state boards, model language dealing with these issues can be developed and adopted by individual states.

## F. Reporting Medication Errors

- 1 To encourage pharmacists to exert leadership in estab-
- 2 lishing a nonthreatening, confidential atmosphere in
- 3 their workplaces to encourage pharmacy staff and oth-
- 4 ers to report actual and suspected medication errors in
- 5 a timely manner; further,
  
- 6 To provide leadership in supporting a single, compre-
- 7 hensive medication error reporting program that (1)
- 8 fosters a confidential, nonthreatening, and nonpunitive
- 9 environment for the submission of medication error re-
- 10 ports; (2) receives and analyzes these confidential reports
- 11 to identify system-based causes of medication errors or
- 12 potential errors; and (3) recommends and disseminates
- 13 error prevention strategies; further,
  
- 14 To provide leadership in encouraging the participation
- 15 of all stakeholders in the reporting of medication errors
- 16 to this program.

(Note: This policy would supersede ASHP policy 9918.)

### Background

As part of sunset review, the Council voted to recommend amending policy 9918 as follows (~~strikethrough~~ indicates deletions):

To encourage pharmacists to exert leadership in establishing a nonthreatening, confidential atmosphere in their workplaces to encourage pharmacy staff and others to report actual and suspected medication errors ~~and adverse drug reactions~~ in a timely manner; further,

To provide leadership in supporting a single, comprehensive medication error reporting program that:

- (a) fosters a confidential, nonthreatening, and non-punitive environment for the submission of medication error reports;
- (b) receives and analyzes these confidential reports to identify system-based causes of medication errors or potential errors; and
- (c) recommends and disseminates error prevention strategies; further,

To provide leadership in encouraging the participation of all stakeholders in the reporting of medication errors to this program.

The Council and Board believed any reference to adverse drug reactions should be deleted, since the policy deals almost exclusively with reporting medication errors. The Council noted that ASHP's Guidelines on Adverse Drug Reaction Monitoring and Reporting address that topic extensively.

## G. Stable Funding for Office of Pharmacy Affairs

- 1 To advocate for adequate funding for the Health Re-
- 2 sources and Services Administration (HRSA) Office of
- 3 Pharmacy Affairs to support its public health mission;
- 4 further,
  
- 5 To support initiatives of the Office of Pharmacy Affairs,
- 6 including the 340B Drug Pricing Program and innovative
- 7 pharmacy service models in HRSA-funded programs.

### Background

The Council and Board discussed the need to support the mission of HRSA and its component Office of Pharmacy Affairs (OPA). Council and Board members reviewed the recent history of funding for OPA. OPA administers the 340B Drug Pricing Program, which requires drug manufacturers to give covered entities (including eligible disproportionate-share hospitals) a discount below average manufacturer prices for brand and generic drugs. OPA also helps administer innovative pharmacy models, such as the Patient Safety and Clinical Pharmacy Services Collaborative. OPA funding since 1992 has come from program management funds and other agencywide funding sources available to the HRSA Administrator. There has not been a dedicated line item in the HRSA budget for OPA. In fiscal year 2008, OPA requested a budget of nearly \$3 million to administer these programs. The Council and Board believed it was important to support the need for a dedicated and stable source of funding to maintain the 340B Drug Pricing Program, clinical pharmacy services, and other patient safety initiatives in order to maintain program integrity and affordable access by indigent patients.

## Board Actions

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

- Compounding by Health Professionals (0411)
- Importation of Pharmaceuticals (0413)
- Home Intravenous Therapy Benefit (0414)
- Management of Blood Products and Derivatives (9919)
- Drug Nomenclature (9011)

## Other Council Activity

**Method-of-Use Patents.** The Council discussed some manufacturers' practice of patenting the procedure associated with the use of a product in an attempt to prohibit generic competition. The Council noted that policy 0814 addressed the need for federal oversight of anticompetitive practices by manufacturers. Furthermore, the Council noted that this area of patent law is unfamiliar to most members and suggested that more research be conducted as to the frequency of this type of method-of-use patents. Council members also noted that it would be timely to provide information to members concerning the role of patent law and the federal Patent and Trademark Office, FDA, and the Federal Trade Commission. All three federal agencies play a role in the marketing and use of medications.

**Cost Benefit as a Factor in Coverage for Unlabeled Use.** The Council discussed the process used to determine coverage for unlabeled use and the various perspectives of patients and family members, employers, government agencies, and payers. The Council noted that payer policies vary in coverage decisions, ranging from step therapy to the use of a medical claim versus a pharmacy claim for expensive unlabeled uses. Council members noted that it is important for compendia to be evidence based and for payers to use the best available evidence in making coverage decisions. Members noted that as revisions are made to the ASHP Statement on the Use of Medications for Unlabeled Uses, the issue of how to deal with cost benefit as a factor in coverage decisions should be considered. Finally, the Council suggested that perspectives of other organizations such as the Academy of Managed Care Pharmacy and the International Society for Pharmacoeconomics and Outcomes Research should be reviewed.

**Interstate Compacts Recognizing Licensure.** The Council discussed the concept of state boards of pharmacy mutually recognizing another state's licensure and allowing a pharmacist to practice in either state. The experience of state nursing boards was examined. The National Council of State Boards of Nursing began a process for mutual recognition of registered nurses and licensed practical or vocational nurses in 1996. Currently, 23 states participate in this mutual recognition model for nursing regulation. A similar process was begun for advanced practice nurse licensure in 2002. In addition, the State Alliance for E-Health (created by the National Governors Association) recommended that NABP gain consensus on a cross-state cooperative pharmacist licensure system to enable a pharmacist to practice across state or territorial lines.

The Council recognized that funding such a mutual recognition system would be an issue for individual state boards. However, the

Council also noted that mutual recognition could help address workforce issues and the need to recognize residents who practice in states outside their state of original licensure. The Council also suggested that mutual recognition could be phased in as the current process of licensure reciprocity is phased out. The Council noted that it would be timely to enter into a dialogue with NABP to further discuss this issue and provide input in the development of model legislation and regulation.

**State Labor Law Classification of Pharmacists.** The Council discussed a delegate Recommendation concerning state law in California that does not consider pharmacists as exempt professional employees unless they are considered executive or administrative employees. The Council acknowledged that this classification affects the training schedule and educational opportunities for residency programs as well as overall flexibility in departmental workload scheduling. The Council expressed concern about the lack of flexibility created by this state law and suggested that this issue be monitored in other states. The Council did note that ASHP policy and philosophy would support the concept that pharmacists are professionals. The Council suggested that ASHP support state affiliates in their advocacy to classify pharmacists as professionals.

**Impact of Government Programs on Drug Costs.** In its discussion regarding funding for the OPA, the Council discussed how various prescription drug coverage and discount programs at the state and federal level influence drug costs. The Council suggested that this topic be an agenda item for a future meeting. In addition, it suggested that ways to educate and inform the membership be explored. Also, coordination with appropriate Sections should be considered.

**Motivation for Patient Referral.** In its discussion on cost benefit as a factor in determining coverage for unlabeled uses, the Council observed the practice of physician referral of patients to hospital outpatient departments. The Council suggested that more information be collected to assess the magnitude of the issue and that members be educated (possibly through a case history) on how hospitals deal with an influx of patients who are referred because of coverage considerations. In addition, the Council noted that some patients request hospitals to administer medications brought from home that may have been provided by another pharmacy. The Council noted that the proceedings of a newly formed Task Force on Caring for Patients Served by Specialty Suppliers would spotlight this issue.



# House of Delegates Session—2009

## 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.

John A. Armitstead, Board Liaison

### Council Members

Lynette R. Moser, Chair (Michigan)  
Douglas Slain, Vice-Chair (West Virginia)  
Jill S. Bates (Illinois)  
Kimberley W. Benner (Alabama)  
Ronald J. Campbell, Jr. (Pennsylvania)  
Kathleen L. Deering (Illinois)  
Steven B. Levy (New York)  
Leslie D. Jagers (Georgia)  
Thomas J. Johnson (South Dakota)  
Patrick J. McDonnell (Pennsylvania)  
Mark J. Sinnott (New York)  
David D. Stenehjem, Student (Minnesota)  
Michael W. Kelly, Section of Clinical Specialists and Scientists Liaison (Iowa)  
Cynthia Reilly, Secretary

### Policy Recommendations

#### A. The Safe and Effective Use of Heparin in Neonatal Patients

- 1 To support the development and use of standardized
- 2 concentrations of heparin for maintenance and flush of
- 3 peripheral and central venous lines in neonatal patients;
- 4 further,
- 5 To advocate that hospitals and health systems use
- 6 manufacturer-prepackaged heparin flush products to
- 7 improve the safe use of heparin in neonatal patients.

#### Background

The preferential use of saline to maintain peripheral lines and devices in adult patients has largely become the standard of care, but use of heparin in neonates continues because of a lack of consensus and perceived and actual limitations in the evidence in published literature. However, fatal medication errors caused by the use of heparin in this patient population have brought to the forefront concern that the risks of using heparin for this purpose may outweigh the potential benefits.

The ASHP Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices, which was published in 1994 and reviewed and revised in 1997 and 2006, respectively, provides evidence for the use of sodium chloride as the preferred solution for maintaining peripheral lines in adult

patients. However, the existing therapeutic position statement (TPS) does not address the use of sodium chloride versus heparin in patients younger than 12 years of age, because at the time of publication there was a lack of sufficient evidence regarding the effectiveness of sodium chloride solution for flushing peripheral lines or maintaining their patency in neonatal and pediatric patient populations.

The Council reviewed evidence from evaluations of the use of 0.9% sodium chloride and heparin to maintain and flush arterial and central lines in neonatal patients and reports of medication errors that involved heparin. The advantages of saline include greater compatibility than heparin with concurrently administered drug therapies, reduced product costs, avoidance of adverse drug events such as heparin-induced thrombocytopenia (a rare but potentially fatal event in this patient population), and the potential to avoid errors caused by improper selection or dilution of heparin products. Advantages of heparin use include extended line patency and a beneficial antithrombotic effect at the insertion site. The Council concluded and the Board agreed that the data are conflicting and insufficient to support the recommendation of a preferred solution for line maintenance in neonatal patients at this time. Confounding factors in this patient population include the type of intravenous access, catheter lumen size, duration of access, and patient variables (e.g., age, weight). The Council believed and the Board agreed that the development of standardized concentrations of heparin to decrease practice variation and the use of manufacturer-prepackaged products are the best ways to improve the safe use of heparin in neonatal patients.

## Board Actions

**Use of Clinical Decision Support to Identify and Manage Drug Interactions.** The Council recommended and the Board voted

To establish, in conjunction with the ASHP Section of Pharmacy Informatics and Technology, a multidisciplinary group or meeting that includes representatives of professional associations, drug information publishers, and software companies to develop consistent standards for the development and inclusion of drug interaction information in clinical decision support systems.

Computerized drug interaction alerts are intended to improve the safe use of drugs, but they often fall short of expectations because of software limitations (e.g., incomplete or incorrect information, improper assignment of severity levels) or user factors (e.g., alert fatigue, overrides). Existing software systems base interaction alerts on information contained in variable drug information databases that use different approaches to assigning severity ratings and clinical significance. In 2001, a study evaluating four drug information compendia found that of the more than 400 drug interactions described in at least one compendium as having major clinical significance, only 2.2% were described similarly in all four compendia. In fact, more than 70% of interactions identified as having major clinical significance in one compendium were not identified as such in the other compendia. The evidence supporting drug interactions is often based on case reports or extrapolated from underpowered studies—situations that do not accurately represent real use conditions and patient-specific variables that affect drug use. Facilities' modifications of software to address the needs of the individual practice site, as well as frequent updates by software vendors that override these modifications, further contribute to the suboptimal results achieved with these software programs. In combination, these factors present significant challenges for health systems, which must balance patient safety, workflow, and productivity.

The Council recommended that ASHP seek collaboration among entities that develop and use drug interaction information in clinical decision support systems to address current limitations in the development and use of these software programs. The collaboration will seek to standardize processes and develop criteria for determining clinically significant drug interactions that can be validated and replicated.

**Therapeutic Position Statement on Strict Glycemic Control in Patients with Diabetes.** The Council recommended and the Board voted

To discontinue the ASHP Therapeutic Position Statement (TPS) on Strict Glycemic Control in Patients with Diabetes.

Tight glycemic control has been demonstrated to reduce morbidity and mortality associated with complications of diabetes, including nephropathy, neuropathy, and retinopathy. This TPS was developed through the Commission on Therapeutics and approved by the Board on July 28, 2003, to address practice variation in managing blood glucose in patients with type 1 and type 2 diabetes and to evaluate patient- and setting-specific factors that should be considered in targeting mean glycosylated hemoglobin (HbA1c) levels recommended by the American Diabetes Association and the American College of Endocrinology (ACE).

The Council recommended that the TPS be discontinued because the current document is outdated. Recent evidence from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) and Action in Diabetes and Vascular Disease: Preterax and Diamicon MR Controlled Evaluation (ADVANCE) trials have the potential to alter best practices for glycemic control, especially in the primary care setting. Substantial practice changes have also occurred in the inpatient setting, including adoption of the ACE recommendation to use correctional insulin therapy in conjunction with monitoring to prevent significant hypoglycemia and increased availability and use of long-acting insulin therapies to meet basal insulin needs. In addition, recent evidence demonstrates that the target level of glycemic control may be less important than controlling the extent of variability in glucose levels in some patient populations in the intensive care unit setting. New devices, including implantable insulin devices that allow for more accurate and continuous monitoring of blood glucose, may also have an impact on practice recommendations. While this information evolves, the Council recommended education as a mechanism to inform clinicians about practice implications of the ACCORD and ADVANCE trials and ACE's policy position discouraging use of sliding-scale insulin.

## Other Council Activity

**Pharmacogenetics and Personalized Medicine.** One of the earliest known genetic variations to affect drug therapy, glucose-6-phosphate dehydrogenase deficiency, results in the breakdown of red blood cells when a person is exposed to certain drugs (e.g., antimalarial drugs, aspirin, nonsteroidal anti-inflammatory drugs, quinidine, quinine, and sulfonamide antibiotics). More recent discoveries include genetic variations that result in variable response to warfarin dosing, use of the CYP 2D6 gene to predict tamoxifen effectiveness, and the establishment of causality for adverse drug reactions that had previously been described as idiosyncratic (e.g., variants in SLCO1B1 associated with an increased risk for statin-related myopathy).

While pharmacogenetic information is growing at an unprecedented pace, the practical application of this evidence to clinical practice is still in its infancy. The extent of genetic biomarker information available in labeling approved by the Food and Drug Administration (FDA) has also increased in recent years, but only a handful of drugs (e.g., abacavir) describe the clinical application of these tests in their prescribing information. The FDA has no requirement that drug product manufacturers complete genetic studies. The Council believed that this field would be greatly enhanced if drug product manufacturers conducted more research (including

practical clinical trials) and if collection and analysis of data on the use of these tests were improved.

The Council recognized that genetics play a significant role in response to drug therapy, but that uncertainties remain about the extent to which genetics affect response and the interplay of genetics with other variables, including concomitant therapies, diet, and other patient-specific factors. There is also limited information about the cost-effectiveness, clinical impact, and implementation of genetic testing and, most important, whether testing improves patient outcomes or avoids adverse drug reactions. Current study design, which includes small populations, also limits the ability to identify the impact of genetic variation, including the strength of correlation between the genotype and perceived effect.

The Council encouraged pharmacists to take a leadership role in determining how pharmacogenetic tests will be applied in the management of drug therapy. The Council suggested that ASHP continue and enhance current efforts to educate members, including information about how genetic tests are developed and approved by the FDA and the benefits and limitations of their use. The need for counter-detailing was recommended because the use of some tests is aggressively promoted to physicians and patients.

**Standardization of Creatinine Assays and Its Impact on Drug Dosing.** The National Kidney Disease Education Program (NKDEP) laboratory working group has implemented two changes that are expected to have a significant impact on pharmacy practice: calibration of serum creatinine assays and automatic laboratory reporting of estimated glomerular filtration rate (eGFR) calculated by the Modification of Diet in Renal Disease (MDRD) equation.

Assay calibration increases the accuracy of laboratory assessments but also results in reported creatinine levels that can be decreased as much as 5–20% from previously reported values. Therefore, it is important that pharmacists and other clinicians know when their laboratory has started using the new assay, which is being phased in with full implementation expected by late 2009.

eGFR is believed to be superior for staging renal function. Its automatic reporting is expected to improve early detection and management of patients with chronic kidney disease, and NKDEP has encouraged practitioners to use this method for estimating GFR instead of the Cockcroft-Gault (C-G) equation. However, application of eGFR to drug dosing is limited because existing pharmacokinetic formulas and dosing information from FDA-approved labeling are based on creatinine clearance calculated by the C-G equation.

While noting the limitations of both equations, the Council believed that, with additional research, clarification, and education, transition to the MDRD equation and eGFR would improve patient care. Information needs were suggested, including identification of high-risk drugs for which the change in dose could be clinically significant and validation of the MDRD equation in different patient populations (e.g., elderly or obese patients). The Council supported the suggestion by NKDEP and others that the FDA issue new guidance directing drug product manufacturers to submit renal dosing information for new drugs using the MDRD equation. ASHP was encouraged to educate pharmacists about the implications of these changes.

**Evaluating and Communicating the Risk of Drug Therapies.** Assessing the potential risk of drug therapies and communicating that risk to patients and other clinicians is a core responsibility of pharmacists, but this responsibility is often complicated by extensive and sometimes competing messages that are presented to health care professionals and patients. Findings reported in the media and elsewhere need to be evaluated in terms of risk versus benefit for the individual patient, including the potential for harm that arises from stopping a therapy prematurely or unnecessarily. Clinicians should also be aware of the potential for liability.

The Council encouraged ASHP to continue current efforts to increase awareness about the need for critical assessment and to provide clinicians with education on assessing and communicating the risk:benefit ratio of therapies. Patient education via [www.safemedication.com](http://www.safemedication.com), media interviews, and other mechanisms was also recommended.

**Benefits and Limitations of Using Data from Clinical Trials to Improve Drug Safety.** Clinical trials for drug approval are intended to demonstrate efficacy and safety of marketed products. However, inherent limitations of preapproval studies (e.g., small sample size and narrowly defined patient populations) frequently necessitate safety-related regulatory actions (e.g., black box warnings, market withdrawals) following FDA approval. Other factors that limit preapproval drug safety efforts include difficulty identifying a cause-and-effect relationship for unanticipated adverse effects and the use of surrogate endpoints that shorten the time to approval and limit the extent of data available. The critical importance of pharmacovigilance, or postmarketing safety surveillance, is highlighted by the Food and Drug Administration Amendment Acts of 2007, which include additional authority for FDA to require postapproval safety studies.

The Council believed this enhanced regulatory authority would improve drug safety, but noted that lack of standardization in reporting adverse events or side effects in clinical trials also contributes to limitations in the current system. Vague terminology (e.g., “the drug was well tolerated”), failure to disclose all study inclusion and exclusion criteria, failure to explain reasons for study withdrawal,

and lack of analysis of data for subpopulations that may be at greater risk are shortcomings in current reporting that limit individual and system-based decision-making. The lack of consistent reporting also makes it difficult to compare results of different trials. Publication bias and lack of data representing negative trial results further limit clinician access to information. The Council reviewed with favor recommendations offered in the 2004 extension of the Consolidated Standards of Reporting Trials (CONSORT) statement (*Ann Intern Med.* 2004; 141:781–8) and suggested that ASHP review and consider endorsing the recommendations.

MedWatch and other spontaneous reporting systems were also noted as cornerstones of improving drug safety. The Council suggested that ASHP continue work with MedWatch and members to standardize reporting and increase the already high rates of pharmacist reporting.

**Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices.** The Council voted to revise the ASHP TPS on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices.

The ASHP Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices was published in 1994 and subsequently reviewed and revised in 1997 and 2006, respectively. The document recommends the preferential use of sodium chloride in adult patients. It does not offer a recommendation for patients younger than 12 years of age, because at the time of publication there was a lack of sufficient evidence on the effectiveness of using sodium chloride in that patient population for flushing peripheral lines or maintaining their patency.

The Council reviewed studies evaluating the use of saline and heparin flush in patients 12 years of age and younger that have been published since the last revision of this TPS in 2006. The Council believed that the availability of new evidence, including data from higher-quality studies, warrants revision of the TPS to recommend preferential use of 0.9% sodium chloride in pediatric patients.

**Use of Drug Interaction Information to Guide Drug Therapy Decisions.** The Council voted to develop guidelines on best practices for the assessment and management of potential drug interactions identified by clinical decision support software and other drug information sources.

Significant variation exists in the implementation and use of drug interaction software in clinical decision support systems. In many health systems, this function is disabled for the prescribing interface in order to address frustration expressed by physicians but is maintained for pharmacy order verification. Some software systems do not permit selective disabling, and some facilities have fully disabled this function for all users.

Prescribers and pharmacists frequently report “alert fatigue” that can lead to the assumption that most alerts are not clinically significant. However, significant liability can result for the prescriber, pharmacy, and pharmacist if failure to recognize and respond appropriately to alerts results in patient harm. Abbreviated references that provide point-of-care drug information (e.g., handbooks, applications for hand-held devices) also contribute to practice variation by providing less complete information.

Although criteria can be developed to identify clinically significant and life threatening interactions, the ultimate decision to use a therapy is based on the patient-specific assessment of risk versus benefit and the availability of alternative treatments. Pharmacists and pharmacy students require education about appropriate strategies for using this information to guide drug therapy for individual patients. The Council recommended that ASHP develop a statement or guideline on best practices for the clinical assessment and management of potential drug interactions that would include strategies for assessing the significance of interactions, including consideration of unique patient characteristics and appropriate documentation of the rationale for how the clinician handled the alert.

**Statement on Evaluating the Quality of Drug Information.** The Council reaffirmed its 2006 recommendation to develop this statement to describe essential components of quality print and electronic drug information resources, including those contained in clinical decision support systems and other technologies. The Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council believed that development of this statement in collaboration with other organizations should be pursued and given highest priority.

**Therapeutic Position Statement on the Preferential Use of Metronidazole for the Treatment of Clostridium difficile-Associated Disease.** The ASHP TPS on the Preferential Use of Metronidazole for the Treatment of *Clostridium difficile*-Associated Disease was approved by the Board on April 22, 1998, and reviewed by the Commission on Therapeutics and the Board in 2002 and found to still be appropriate. In 2007, the Council recommended revision of this document, noting that it continues to be an important resource for clinicians, especially in light of the emergence of more virulent strains of *C. difficile* and the addition of fluoroquinolones as major contributors to the development of *C. difficile*-associated disease. The 2008 Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council noted that the Infectious Diseases Society of America is nearing completion of a guidance document on this topic and recommended that ASHP review that guideline, when available, to determine if there is a continued need for ASHP's document.

**Therapeutic Position Statement on the Safe Use of Oral Nonprescription Analgesics.** The ASHP Therapeutic Position Statement on the Safe Use of Oral Nonprescription Analgesics was approved by the Board on November 14, 1998. In 2003, the Commission on Therapeutics recommended that the document remain active while a revision was developed. The Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development and recommended that development of this guidance document be continued because of the significant safety risk posed by inappropriate use of these therapies.

**Therapeutic Position Statement on the Use of Perioperative Antibiotic Irrigations.** In 2005, the Commission on Therapeutics recommended development of this document to address the lack of consensus about the effectiveness of using perioperative antibiotic irrigations to prevent surgical site infections. The Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council believed that the use of antibiotic irrigations continues; therefore there would be benefit in developing an official ASHP guidance document to provide support to pharmacy staff who receive requests to compound antibiotic irrigations.

**Therapeutic Position Statement on the Safe Use of Pharmacotherapy for Obesity Management in Adults.** The Board approved this guidance document on April 23, 2001; in 2006, the Council reviewed the document and recommended that it remain active while a revision was developed. The Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council noted an ongoing need for this document but recommended that its development be assigned lower priority than other documents scheduled for development or revision.

**Therapeutic Position Statement on the Use of Corticosteroids for Pediatric Patients with Asthma.** In 2007, the Council reviewed a draft outline for this document and provided recommendations for revision. The 2008 Council re-examined the need for this TPS as part of its evaluation and prioritization

of guidance documents scheduled for development. The Council recommended that development of this document be discontinued in light of the increased awareness that inhaled corticosteroids are the standard of care for treatment of asthma in this patient population and the recent publication of the National Asthma Education and Prevention Program guidelines that meet the information need intended for this TPS.

**Statement on the Use of Antidepressants in Children and Adolescents.** In 2007, the Council reviewed the controversy surrounding the use of antidepressants in pediatric and adolescent patients, including conflicting evidence on the potential for these therapies to increase suicidality in these patient populations, and recommended that ASHP develop a statement describing appropriate management of these drug therapies, including monitoring and adjuvant therapies (e.g., counseling). The 2008 Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council determined that a commentary in *AJHP* or educational programming would better meet the need for information this statement was intended to address.

**Therapeutic Position Statement on the Recognition and Treatment of Depression in Older Adults.** In 2002, the Commission on Therapeutics recommended revision of the ASHP Therapeutic Position Statement on Recognition and Treatment of Depression in Older Adults, which was approved by the Board on September 18, 1998. The Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council recommended that development of this document not be pursued because awareness of depression in the elderly has increased dramatically and there are numerous guidelines available on detection and treatment of this condition.

**Therapeutic Position Statement on the Treatment of Tuberculosis.** The ASHP Therapeutic Position Statement on Strategies for Preventing and Treating Multidrug-Resistant Tuberculosis was first approved by the Board of Directors on November 16, 1996. In 2000, the Commission on Therapeutics completed a sunset review of this guidance document and recommended revision; in 2007, the Council reviewed a draft manuscript and recommended strategies to uniquely position the document in light of recent guidance available from the Centers for Disease Control and Prevention (CDC). The 2008 Council re-examined the need for this guidance document as part of its assessment and prioritization of therapeutic guidance documents scheduled for development. The Council recommended that development of this document not be pursued based on the availability of quality and comprehensive guidelines from other sources, including the CDC. A commentary in *AJHP* or educational programming was suggested as mechanisms that would meet the need for information this statement was intended to address.

**Recommendations for Development of ASHP Therapeutic Guidance Documents.** The Council recommended strategies for improving the timeliness and usefulness of ASHP's therapeutic guidance documents, based on a review of the Society's Best Practices Improvement Initiative, excerpts from the Institute of Medicine report, *Knowing What Works in Health Care*, and other resources. The Council recommended continued collaboration with other guideline developers (including the establishment of multidisciplinary expert panels) and use of a consistent system for grading evidence and strength of recommendations. Inclusion of comparative effectiveness information is desirable, but often limited by the quality of available evidence and the perspective (i.e., payor, provider, or the payer) selected by the study authors. The Council suggested that cost-effectiveness information should be included in ASHP guidelines when information is available and valid. Strategies for including this information could be based on recommendations that appear in the chapter "Strategies for Including Resource Allocation and Economic Considerations" in *Antithrombotics and Thrombolytic*

*Therapy: American College of Chest Physicians (ACCP) Evidence-Based Clinical Practice Guidelines*, 8th ed.

Other Council suggestions included increasing the transparency of the guideline development process, promoting opportunities for member participation in guideline development and review, and providing readily accessible information about the status of guidelines in development. An evaluation of the optimal time frame for sunset review of therapeutic guidelines was also recommended.

**Recommendations for Comparative Effectiveness Research.** The Council discussed potential clinical research topics for submission to the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care (EHC) program, which conducts comprehensive reviews of existing evidence on the relative benefits and risks of alternative interventions or generates new scientific evidence in situations in which the existing evidence is not sufficient to respond to a specific research question. A Council subcommittee will work with ASHP and AHRQ staff to prepare one or more formal submissions to the EHC program.