



SEIZE THE INITIATIVE

ASHP House of Delegates 2012
June 10 and 12, 2012

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Board of Directors Reports on Councils. ASHP councils met in Bethesda, Maryland, September 19–21, 2011. Each report has three sections: Policy Recommendations (new policies initiated by the council, approved by the Board of Directors, and subject to ratification by the House of Delegates); Board Actions (Board of Directors consideration of council recommendations that did not result in new policies, and actions by the Board in areas for which it has final authority); and Other Council Activity (additional subjects the council discussed, including issues for which it has begun to develop policy recommendations). The House will consider two additional policy recommendations approved by the Board of Directors, one from the Section of Clinical Specialists and Scientists and another from the Pharmacy Student Forum and the Section of Pharmacy Informatics and Technology.



SEIZE THE INITIATIVE

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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.

Lisa M. Gersema, Board Liaison

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Policy Recommendations



A. Preceptor Skills and Abilities

- 1 To collaborate with pharmacy organizations on the development of standards to
- 2 enhance the quality of experiential education and pharmacy residency precepting;
- 3 further,
- 4 To provide tools, education, and other resources to develop preceptor skills.

Rationale

The quality of pharmacy education is directly tied to the quality and effectiveness of its preceptors. Growth in the number and size of colleges of pharmacy has increased demand for teaching sites and for qualified preceptors to provide experiential training and residency rotations at those sites. As a result, teaching sites are often selected with little proof of the quality of the site or the ability of its preceptors, and many of those preceptors lack experience or training in teaching and precepting students and residents. Although nearly all colleges of pharmacy try to provide preceptor training, their efforts to develop preceptors are often inconsistent and ineffective due to resource constraints. In addition to improved training of preceptors, the profession needs a mechanism for evaluating the skills of preceptors and teachers.

There has been little coordination of preceptor development at the national level. The quality and effectiveness of preceptors is important to the entire profession and deserves a national platform and dedicated resources.

Background

The Council discussed the importance of precepting and teaching skills and the long-term impact good preceptors have on the readiness of pharmacy and residency graduates. The Council reviewed the resources available for preceptor development from various organizations and concluded there a need for more programs, especially those that focus on increasing effectiveness rather than simply providing a checklist.

The Council also noted that different skills sets are needed to be effective, depending on the type and level of student (i.e., introductory pharmacy practice experience [IPPE] students, advanced pharmacy practice experience [APPE] students, or residents).

The Council stated that the profession also needs a mechanism for evaluating the skills of preceptors and teachers. The Accreditation Council for Pharmacy Education (ACPE) provides guidance on preceptor qualifications, but the Council was not certain that ACPE adequately describes the essential requirements of a preceptor. The Council also discussed how some state boards of pharmacy (currently 24) license or register pharmacist preceptors. Requirements for state recognition of preceptors varies greatly, with many states silent on the quality or

qualifications of the preceptor, requiring only that preceptors be licensed and in good standing with the board. The Council felt strongly that an inconsistent patchwork of state board of pharmacy requirements for preceptor qualifications could deter or complicate the development of more and better-qualified preceptors.



B. Qualifications and Competencies Required to Prescribe Medications

- 1 To affirm that prescribing is a collaborative process that includes patient assessment,
- 2 diagnosis, evaluation of available treatment options, monitoring to achieve therapeutic
- 3 outcomes, patient education, and adherence to safe and cost-effective prescribing
- 4 practices; further,

- 5 To affirm that safe prescribing of medications, if performed independently, requires a
- 6 practitioner who is competent and knowledgeable in all these processes, or, if performed
- 7 collaboratively, requires that competent, interdependent professionals complement each
- 8 others' strengths at each step; further,

- 9 To explore the creation of prescribing standards that would apply to all who initiate or
- 10 modify medication orders or prescriptions and that would facilitate development of
- 11 competencies and training of prescribers; further,

- 12 To encourage research on the effectiveness of current educational processes designed to
- 13 train prescribers.

Rationale

Debate about health care providers' evolving scopes of practice, focused primarily on prescribing privileges, has raised the question of what training and competencies should be required of current or potential prescribers. The increasing complexity of medication use, growing diversity of professionals authorized to prescribe, and continuing high incidence of adverse drug events call for the development of standards for prescribing and further development of associated competencies and training requirements.

Background

The Council discussed whether a minimum level of training should be established in order to prescribe medications. The Council reviewed studies from other countries in which new physician graduates were surveyed on their confidence and readiness to prescribe, along with objective evaluation of new medication prescriptions they had written. A high percentage of respondents did not feel capable of prescribing independently, and the review of their prescriptions showed many errors, some potentially lethal. Unfortunately, these types of studies have not been conducted with U.S.-trained physicians or other prescribers. Anecdotal

evidence suggests that new graduate medical residents make more errors than their experienced counterparts, especially when they first enter practice and start to prescribe medications.

The Council discussed the predicted shortage of physicians, especially in primary care. This shortage, and the long lead time to train more physicians, might result in a need and an opportunity for others who are trained and qualified to prescribe and manage patients' treatment regimens.

The Council discussed the need to describe core competencies needed to prescribe medications but concluded that ASHP is not in a position to do so independently. The need for additional research and identification of data that support the case for medication-specific competencies was also discussed.

The Council also noted that there is a spectrum of prescribing: at one end, independent prescribing, and at the other, team-based approaches to care and medication therapy management. Team-based care models that build on strengths of individual team members have been shown to be most effective in producing the desired therapeutic outcomes. The value of team-based care and the collective benefit from teams would also be important to the broader discussion of prescriber competencies and training.



C. Qualifications of Pharmacy Technicians in Advanced Roles

- 1 To recognize that highly trained and skilled pharmacy technicians working in
- 2 advanced roles regularly perform complex and critical medication-use procedures,
- 3 and that a safe and effective medication-use process depends significantly on the
- 4 skills, knowledge, and competency of those pharmacy technicians to perform those
- 5 tasks; further,

- 6 To reaffirm that all pharmacy technicians should complete an ASHP-accredited
- 7 training program, be certified by the Pharmacy Technician Certification Board, and be
- 8 licensed by state boards of pharmacy; further,

- 9 To advocate that beyond those requirements pharmacy technicians working in
- 10 advanced roles should have additional training and should demonstrate
- 11 competencies specific to the tasks to be performed; further,

- 12 To advocate that expansion of pharmacy technician duties into expanded, advanced
- 13 roles should include consideration of potential risk to patients and that ongoing
- 14 quality assurance metrics should be established to assure patient safety.

Rationale

A growing number of hospitals utilize pharmacy technicians in advanced or specialized roles beyond those traditionally filled by technicians: medication preparation, distribution, and purchasing. These advanced or specialized roles include performing medication reconciliation, collecting laboratory data, and managing automation and technology, among others. While there has been a good deal of discussion about minimum standards for education and training of pharmacy technicians in general, there has been little discussion about technicians in these specialized roles. These advanced roles will require different skills and competencies, and pharmacy technicians will require additional, task-specific training and should demonstrate competency before being allowed to perform such tasks. Hospitals and health systems will need to consider the potential risk to patients of expanding the roles of pharmacy technicians and establish quality assurance metrics to assure patient safety.

Background

The Council discussed a previous recommendation made to the ASHP Board of Directors in 2010 but referred back by the Board so that it could be reconsidered in light of the [recommendations from the Pharmacy Practice Model Initiative \(PPMI\) Summit](#), which occurred after the Council deliberations. The Council reiterated that having pharmacy technicians performing these advanced roles benefits the pharmacy practice model and therefore ultimately benefits patients.

The Council discussed the inconsistencies at the state level regarding pharmacy technician education and training, certification, and registration or licensure, and how this creates challenges for advancing roles and care. The Council stated that a minimal level of training for the core roles of pharmacy technicians is critical, and there was consensus that these training elements are addressed in the [Model Curriculum for Pharmacy Technician Training](#) used as part of program accreditation.

The Council also discussed the need to describe a scope of practice for pharmacy technicians, including boundaries permitting technicians to make “professional” judgments while not being authorized or allowed to make “clinical” judgments. Examples of professional judgments included technicians performing IV drip rounds and using their judgment to determine when the next infusion would be needed and ordering it accordingly, or interviewing patients to obtain a medication list that would be used as part of a medication reconciliation process. Examples of a clinical judgment would be counseling patients on use of their medications or providing advice on which over-the-counter medication was appropriate for their clinical situation.

The Council concluded that pharmacy technicians in these advanced roles should receive additional training specific to the tasks to be performed and should demonstrate task-specific competencies as well. The need to identify additional training elements for nontraditional, advanced roles was also discussed. Finally, the Council noted the importance of having hospitals and health systems consider the potential risk to patients of having pharmacy technicians in advanced roles and establish quality assurance metrics to assure patient safety.



D. Role of Students in Pharmacy Practice Models

- 1 To encourage pharmacy practice leaders to incorporate students, including those in
- 2 introductory and advanced pharmacy practice experiences and interns, into active,
- 3 meaningful roles in new and evolving practice models.

Rationale

Many pharmacy departments are re-evaluating their pharmacy practice models and changing how pharmacists, pharmacy technicians, and automation are utilized in the provision of safe and effective medication use. A few departments have actively sought to incorporate pharmacy students into their practice models, and those that have done so have been able to show a significant improvement in students' IPPE, APPE, and internship experiences. Building in these roles as models are changed will result in benefits not only for the pharmacy department and the patients they serve, but also for students who will learn from having a more engaged, meaningful role in delivering patient care.

Background

The Council discussed PPMI Recommendation B26c, which reads: "Every pharmacy department should develop a plan to allocate pharmacy student time to drug-therapy management services." There was strong support for and concurrence with this recommendation.

Some sites use pharmacy interns as pharmacist extenders, using a structured internship that builds on graduated skill development by the student over time. Upon reaching a certain level of skill, students are permitted, for example, to give counseling for heart failure patients at discharge, facilitate drug conversion programs, perform medication reconciliation, and administer pneumococcal vaccinations. It is important that interns commit to working at the site for a period of time, though, so that the training time and cost is offset during the intern's tenure.

The limited number of currently available internship positions was also discussed. Students are often unable to find available positions, especially in geographic areas that have more than one college of pharmacy and therefore a high concentration of students. Positions are limited in both hospital and community pharmacy settings. A degree of flexibility may be required with internship positions, and this flexibility may need to be considered when institutions are structuring their staffing models (e.g., requiring traditional work shifts each week might not always work). Sites that have addressed this need for flexibility have reported a positive experience with interns. Examples of successful innovations include establishing a structured program that operates in summer months only, thereby avoiding conflict with rotations or classes, and hiring a pool of interns who are able to cover for each other when classes or rotations create a conflict, effectively placing the burden on the intern to see that his or her shift is covered. ASHP should promote those practice models and settings that effectively utilize interns.

State laws regarding student roles were discussed as a possible limitation. For example, some states require “direct supervision” of students, potentially limiting the roles students might play. Some states have worked to standardize schedules, goals and objectives, expectations, and logistical considerations for IPPE and APPE students in specific regions. This coordination has facilitated better scheduling and inclusion of students in practice models, and sites are better able to anticipate the skills and abilities of students assigned to them.



E. ASHP Statement on the Role of the Medication Safety Leader

- 1 To approve the ASHP Statement on the Role of the Medication Safety Leader ([Appendix](#)).

Background

At its 2010 meeting, the Council discussed how the role of medication safety officers varies from institution to institution and examined the challenges people working in such positions frequently encounter. The Council voted to develop an ASHP statement on the role and responsibilities of the pharmacist charged with leadership on improving safety of medication-use systems (i.e., the medication safety officer). The Section Advisory Group on Medication Safety of the ASHP Section of Inpatient Care Practitioners convened a workgroup to draft the statement, which was reviewed by more than 30 ASHP members and subsequently endorsed by the Section’s Executive Committee.



F. “P.D.” (Pharmacy Doctor) Designation for Pharmacists

- 1 To discontinue ASHP policy 0217, which reads:
 - 2 To oppose the use of “P.D.” or any other designation that implies an
 - 3 academically conferred degree where none exists.

Background

As part of sunset review, the Council reviewed policy 0217 and concluded it is no longer needed. The use of arbitrary designations to describe pharmacists or imply an academic degree is no longer an issue. The Council agreed that the use of P.D. or similar designations was inappropriate and could lead to confusion. Many of the efforts to establish these designations were in response to the transition to the Doctor of Pharmacy as an entry-level degree. Now that the transition has occurred, proposals to create such designations have subsided, making this policy unnecessary. The Council recommended and the Board voted to discontinue the policy.



G. Substance Abuse and Chemical Dependency

- 1 To discontinue ASHP policy 0209, which reads:
 - 2 To collaborate with appropriate professional and academic organizations in
 - 3 fostering adequate education on substance abuse and chemical dependency
 - 4 at all levels of pharmacy education (i.e., colleges of pharmacy, residency
 - 5 programs, and continuing-education providers); further,
 - 6 To support federal, state, and local initiatives that promote pharmacy
 - 7 education on substance abuse and chemical dependency; further,
 - 8 To advocate the incorporation of education on substance abuse and
 - 9 chemical dependency into the accreditation standards for Doctor of
 - 10 Pharmacy degree programs and pharmacy technician training programs.

Background

As part of sunset review, the Council reviewed existing ASHP policy 0209. There was discussion of whether the policy should be broadened to include education of the public on substance abuse and whether abuse of prescription drugs should be explicitly added. After reviewing the [ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance](#), the Council concluded that the statement was more comprehensive and was sufficient in expressing ASHP's position on the issue and that ASHP policy 0209 was no longer needed. The Council recommended and the Board voted to discontinue the policy.

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.)

- [Requirement for Residency](#) (0701)
- [Pharmacy Technician Training](#) (0702)
- [ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process](#) (0705)
- [Image of and Career Opportunities for Pharmacy Technicians](#) (0211)
- [Pharmacists' Role in Immunization and Vaccines](#) (0213)
- [Educational Program Resources for Affiliated State Societies](#) (0215)
- [Career Counseling](#) (8507)

Other Council Activity

Evaluating Competency of Experienced Pharmacists

The Council discussed a House of Delegates recommendation suggesting that ASHP develop guidance for managers on how to evaluate competency and skills of experienced pharmacists. The use of credentials, experience, and training was discussed, but actually measuring competency remains an obstacle. Council members provided examples of individuals who had impressive resumes, with degrees, residencies, board certification, and experience, but yet were not effective clinicians.

The Council concluded with the need to reaffirm the value of an effective privileging and credentialing process and advocate that hospitals and health systems ensure their processes work. Individual use of continuing professional development (CPD) was also considered to be a positive attribute when considering candidates, and the Council suggested ASHP continue to offer [resources and information on CPD](#).

Licensure of Pharmacy Technicians by State Boards of Pharmacy

The Council discussed a recommendation from the ASHP PPMI Summit calling on ASHP to revise its stance from registration of pharmacy technicians by state boards of pharmacy to licensing of pharmacy technicians.

Council members concurred that licensure should be predicated on completion of an ASHP-accredited training program, and while this might not be feasible with the current number of training programs, it should be a goal. Stating why ASHP supports this position will also help in building the case at the state level.

There was recognition that a requirement for licensure would create challenges for health systems and pharmacies in rural areas, where training programs and qualified staff are more difficult to find. Given the important role that pharmacies play in these rural locations, the need for well-qualified pharmacy personnel will be even more acute. Others noted that states that set a requirement for training ultimately witnessed many new training programs emerge to meet the new market need.

The Council discussed the need to better define the roles pharmacy technicians should be able to perform independently and which depend on the oversight of a pharmacist. These roles should be included in a “scope of practice” for pharmacy technicians, and the scope for a licensed pharmacy technician should be distinctly different from that of a registered or unlicensed individual. The Council agreed that both completion of an ASHP-accredited training program and certification by the Pharmacy Technician Certification Board should both be minimum requirements for licensure.

Board Certification of Pharmacists

The Council discussed the new business item on board certification submitted by the ASHP Section of Clinical Specialists and Scientists. The Council generally was in agreement with the new business item but did pose some additional questions and possible revisions.

Regarding the principle that pharmacists should become board certified where certification exists, the Council agreed but concluded that this goal is aspirational and needs to be stated as such. The Council concurred that there is value in specialty certification but also affirmed that the real value was in the training that leads up to certification more than in the certification itself. There was also recognition that goals on certification will take time.

Residency Capacity

The shortage of residency positions in relationship to applicants continues to be an issue for the profession. The Council reviewed the gap between applicants and positions for the most recent residency match and discussed what the needs for residents are likely to be in the future. The need for ASHP to act on recommendations from the stakeholders meeting was reinforced, targeting potential residency sites, providing resources, and assisting new programs in as many ways as possible.

The value of promoting innovative and new models of residency was also wholeheartedly supported by the Council, such as nontraditional programs and an “attending” pharmacist model in which residents and students provide care with oversight.

Education and Training of the Medication-use Systems and Technology (MST) Pharmacy Specialist

The concept of an MST Pharmacy Specialist was discussed by the Council, with the goal of providing feedback on the need for such a position and what its education and training needs might be.

The MST specialist position would have a role in pharmacy operations, distribution oversight, pharmacy automation used for dispensing, medication safety, quality improvement, technology oversight and training, USP 797 compliance, waste stream management, and education and training. There are people in these types of positions in many hospitals, but generally they have developed skills through on-the-job training and have not had a structured method of training and development.

The Council supported the need for these types of positions and concurred conceptually with the residency model proposed. The need to get the right drug to the right patient at the right time has never been more critical, and drug therapy is only becoming more complex.

Council members noted that the MST specialist should be a pharmacist. Some gave examples of hospitals using industrial engineers in a similar role, creating unique challenges because these people don’t understand how medication systems work and interface. The Council also discussed likely reporting relationships for such a position, with a clear preference that MST specialist report to the pharmacy director rather than some other department.

Appendix



ASHP Statement on the Role of the Medication Safety Leader

Position

1 The American Society of Health-System Pharmacists (ASHP) believes that medication safety
2 is a fundamental responsibility of all members of the profession of pharmacy. For a
3 medication safety program to succeed, however, it is essential that there be an innovative
4 leader to set a vision and direction, identify opportunities to improve the medication-use
5 system, and lead implementation of error-prevention strategies. The medication safety
6 leader's role includes responsibility for leadership, medication safety expertise, influencing
7 practice change, research, and education. ASHP believes that because of their training,
8 knowledge of the medication-use process, skills, and abilities, pharmacists are uniquely
9 qualified to fill the roles and meet the responsibilities of the medication safety leader in
10 hospitals and health systems.

Background

11 Hospital and health-system pharmacists have improved pharmacy systems over the past 60
12 years to reduce the risk that medications could harm patients. Medication safety was at the
13 heart of such historic innovations in pharmacy services as unit-dose systems, decentralized
14 clinical pharmacy services, and intravenous admixture services. The crucial leadership role
15 of pharmacists in medication safety has been summarized as follows:

16 Pharmacy leadership is the core of a successful medication safety program.
17 Pharmacy leaders can play an enormously important role in performance
18 improvement. They can be part of the senior leadership team's DNA because
19 their impact and view go far beyond the walls of the pharmacy.... Pharmacists
20 can play an important role as leaders to reduce patient safety risks, optimize
21 the safe function of medication management systems, and align pharmacy
22 services with national initiatives that measure and reward quality
23 performance.¹

24 The landmark Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health*
25 *System*² generated major patient safety initiatives by government agencies, regulatory and
26 accrediting bodies, professional and organizational associations, and health care
27 organizations. The Joint Commission (TJC) National Patient Safety Goals (NPSGs)³ are an
28 example of a response to the original IOM report. The Pharmacy Practice Model Initiative
29 (PPMI)⁴ and the National Quality Forum (NQF) Safe Practice 18⁵ incorporate medication
30 safety principles to ensure optimal patient safety and outcomes.

31 The medication safety leader (also referred to as a medication safety officer,
32 medication safety manager, or medication safety coordinator, among other titles) is a
33 clinical practitioner designated by an organization to serve as the authoritative expert in
34 safe medication use. Traditionally, the medication safety leader has been a clinical
35 pharmacist or manager within the department of pharmacy, although the position is

36 sometimes filled by a nurse or physician. The medication safety leader may report to the
37 organization's risk management department, its office of quality, or to a senior
38 administrator (e.g., hospital vice president, chief medical officer, or chief executive officer).
39 Reporting outside the pharmacy department may foster interdisciplinary approaches to
40 medication safety. Medication safety leadership may encompass a single hospital or a group
41 of organizations (e.g., spanning a health system or at a corporate level of a larger
42 organization). Regardless of organization size, it is critical that the fundamentals of
43 medication safety are the central component of the medication safety leader's job function.
44 Although medication safety leaders may have other responsibilities in smaller institutions,
45 medication safety should remain their core responsibility, and they must be strategically
46 positioned and empowered to lead efforts to reduce the risks of medication use.

47 The characteristics of a medication safety leader include:

- 48 1. A strong understanding of the facility's internal systems and processes developed
49 through firsthand experience, observations, medication-use evaluations, interviews,
50 and data analysis for a spectrum of patient populations (e.g., pediatric, geriatric,
51 cardiac, oncology).
- 52 2. Clinical expertise and a broad understanding of health care systems and processes to
53 facilitate accurate interpretation of clinical events.
- 54 3. Knowledge of and experience with all aspects of the medication-use system, including
55 procurement, prescribing, transcribing, preparation, distribution, administration,
56 documentation, and monitoring.
- 57 4. Strong analytical skills and an understanding of statistics, population data, and the
58 concepts of risk and prioritization.
- 59 5. Knowledge of performance improvement methodology and tools, including root cause
60 analysis (RCA), failure mode and effects analysis (FMEA), cause-and-effect
61 diagramming, process-flow mapping, and methods for monitoring projects and
62 measuring the progress of performance improvement initiatives.
- 63 6. Three or more years of post-training health-system practice experience.
- 64 7. Demonstrated leadership skills.
- 65 8. Excellent small and large group presentation skills.
- 66 9. Excellent verbal communication skills, especially the ability to communicate to all types
67 of health care providers, as individuals as well as in small and large groups.
- 68 10. Excellent writing and editing skills.
- 69 11. Strong personal belief that resolving the problem of medication errors is a systems
70 issue and not an individual health care provider issue.
- 71 12. Ability to function proactively rather than reactively.
- 72 13. Strong personal belief in the concept of a "just culture"⁶ that enhances transparency,
73 opens participation to all health care professionals, and fosters a "lessons learned"
74 environment in an organization's medication-error reporting system.
- 75 14. Understanding of concepts and application of safety principles, continuous quality
76 improvement, and human factors engineering.
- 77 15. Appropriate assertiveness.
- 78 16. A passion for medication safety and improving patient outcomes.
- 79 17. Proven success in working with interdisciplinary teams and engaging diverse groups.
- 80 18. Strong personal belief in engaging patients as part of the health care team.

81 19. Eagerness to learn from events outside one's own facility (e.g., through external
82 sources of information) to apply learning about what went wrong in order to identify
83 and remedy possible system weaknesses to prevent patient harm.⁷

84 The scope of a medication safety leader's responsibilities reaches into every corner of the
85 health care system and encompasses many roles, such as educator, preceptor, mentor,
86 detective, compliance officer, risk manager, engineer, accountant, statistician, computer
87 analyst, and counselor. A typical day may include attending safety rounds, precepting
88 pharmacy students and residents, writing policies, reviewing adverse drug reactions and
89 medication error reports, developing error-prevention strategies, leading process
90 improvement teams, implementing action items, reviewing smart pump libraries, ensuring
91 safe use of automated medication dispensing systems, assessing the safety of replacement
92 drug products during drug shortages, orienting new professional staff, assisting with
93 medication reconciliation, conducting tracers to ensure compliance with accreditation
94 standards (e.g., TJC medication management standards and NPSGs), working with
95 practitioners to resolve acute events, attending medical staff meetings, or educating the
96 corporate board on the culture of safety. Most medication safety leaders quickly find
97 themselves involved in many projects and committees as well as serving as the contact
98 person when nursing, pharmacy, or medical staff have questions or problems. The
99 medication safety leader needs a solid understanding of patient safety principles and must
100 have the ability to prioritize work activities to have a positive impact on the safety of patient
101 care. The medication safety leader should strive to acquire additional skills crucial to
102 success, such as presentation and communications skills, as well as expertise in process
103 improvement methodologies such as Six Sigma and Lean. Formalized training in medication
104 safety can be achieved through residency, fellowship, certificate programs, and other
105 methods of continuing education. ASHP supports the expansion of pharmacy education and
106 postgraduate residency training to include an emphasis on medication safety.⁸

Responsibilities of Medication Safety Leaders

107 Medication safety leaders must collaborate with all types of health care professionals,
108 support staff, and management, and consider all components of the medication-use process
109 in both inpatient and clinic settings in order to improve medication safety. The medication
110 safety leader's role includes responsibility for leadership, medication safety expertise,
111 influencing practice change, research, and education.

112 **Leadership.** To provide leadership, the medication safety leader will:

- 113 1. Develop a vision of an ideal safe medication-use system for the organization.
- 114 2. Oversee the planning, creation, review, and refinement of a medication safety plan.
- 115 3. Proactively develop and lead implementation of error-prevention strategies based on
116 practice standards, literature review, medication safety tools, and analysis of the
117 organization's medication safety data.
- 118 4. Participate in the planning, design, and implementation of the organization's
119 medication-use technology and automation systems.
- 120 5. Build a culture of safety through "lesson learned" education and communication across
121 the entire organization.
- 122 6. Oversee processes to collect information on the organization's medication errors and
123 system failures to ensure that they are captured and barriers to reporting are

- 124 addressed.
- 125 7. Ensure compliance with state and federal regulatory and legal requirements relating to
126 medication safety, and assist in the accreditation process by ensuring that the
127 organization's medication-use processes meet applicable medication management
128 standards and NPSGs.

129 **Medication safety expertise.** In the role of medication safety expert, the medication
130 safety leader will:

- 131 1. Serve as an authoritative resource on medication safety for the organization.
- 132 2. Contribute the medication safety perspective for technology initiatives.
- 133 3. Contribute the medication safety perspective to internal and external emergency
134 preparedness planning.
- 135 4. Serve as an internal consultant to investigate medication safety events or issues and
136 develop recommendations for action.
- 137 5. Serve as the chair of the Medication Safety Committee, whose duties may include
138 setting the agenda, reviewing general and specific error reports, and examining the
139 progress of projects and initiatives assigned to the medication safety team.
- 140 6. Be knowledgeable in the application and use of a variety of quality improvement
141 methodologies and tools (e.g., FOCUS-PDCA or Lean methodologies, root cause
142 analysis, failure mode and effects analysis).
- 143 7. Collect, review, and analyze, as the leader of review teams, the organization's
144 medication-use, medication error, adverse drug reaction, and continuous quality
145 improvement data (e.g., markers of adverse drug events, smart pump event data,
146 triggers and surveillance information, and automated dispensing system and bedside
147 barcode scanning reports) and use appropriate data analysis techniques to identify
148 needed improvements and develop high-leverage error-reduction strategies.
- 149 8. Predict and prepare to manage medication safety issues caused by potential or actual
150 drug product shortages and the use of replacement drug products.
- 151 9. Maintain knowledge of trends and developments in the patient safety field through
152 continuous professional development; reading articles, journals, and related material;
153 attending appropriate seminars, conferences, or educational programs; and utilization
154 of information from the Institute of Safe Medication Practices (ISMP) National
155 Medication Error Reporting Program, the Food and Drug Administration (FDA)
156 MedWatch program, and similar programs.
- 157 10. Participate at a local and national level in patient safety and medication safety
158 organizations and initiatives.

159 **Influencing practice change.** To influence practice change, the medication safety
160 leader will:

- 161 1. Collaborate with other departments (e.g., pharmacy, risk management, and patient
162 safety), hospital or health-system senior leadership, frontline staff, and nursing and
163 medical staff leadership to identify and prioritize safety issues and develop risk-
164 reduction strategies using the methods listed above to identify opportunities to
165 improve medication safety.
- 166 2. Manage changes in the medication-use system to enhance medication safety, ensure
167 that appropriate measures are taken to address and resolve medication safety issues,

- 168 and see that hospital staff and faculty are supported in providing safe care for patients.
- 169 3. Work closely with others (e.g., the patient safety officer) to integrate medication safety
170 into the overall strategic plan for patient safety and coordinate medication safety
171 initiatives with organizational patient safety initiatives.
- 172 4. Participate in or lead multidisciplinary hospital and health-system committees
173 concerned with medication errors, adverse drug events and reactions, near misses,
174 policy review, safe medication use, new product review, and patient safety to identify
175 risk points and prioritize system improvements to reduce the potential for medication
176 error and patient harm.
- 177 5. Consult with and advise specific clinical teams and the hospital and health system
178 generally on opportunities and strategies to improve patient care.
- 179 6. Encourage organization-wide medication error reporting through an established and
180 accepted error reporting system that utilizes appropriate error detection methods
181 (e.g., trigger tools) and through other appropriate avenues such as the Pharmacy &
182 Therapeutics Committee, Medication Safety Committee, or Patient Safety Committee.
- 183 7. Develop effective methods for spreading best medication-use practices throughout the
184 organization.
- 185 8. Use continuous quality improvement principles to assess and report on the status of
186 efforts to improve medication safety.
- 187 9. Periodically review and update clinical decision support tools to alert staff to high-risk
188 situations and educate staff as needed.

189 **Research and education.** To further research and education regarding medication
190 safety, the medication safety leader will:

- 191 1. Design and assist in the implementation of education and orientation programs in safe
192 medication use, including:
- 193 • development of competency assessment for staff tasks related to medication
194 safety (e.g., use of smart pumps and automated medication dispensing
195 systems);
 - 196 • education of health care providers, other pertinent staff, and (as possible)
197 patients to ensure they are competent in safe medication-use practices; and
 - 198 • provision of effective ongoing programs and presentations related to safe
199 medication use to diverse audiences (e.g., nursing, pharmacy, respiratory
200 care, and medical staff).
- 201 2. Share information about actual or potential medication errors or harm with safety
202 organizations such as the Institute for Safe Medication Practices (ISMP), the FDA, drug
203 or product manufacturers, and state error reporting programs.
- 204 3. Conduct medication-use safety research through well-designed, externally validated
205 studies, and implement evidence-based practices for medication safety.
- 206 4. Contribute to the literature on medication safety.
- 207 5. Provide medication safety education to pharmacy colleagues, students, and residents,
208 as well as other health care professionals.
- 209 6. Integrate medication safety into orientation and training for all health care providers
210 who participate in the medication-use process.

Conclusion

211 ASHP believes that pharmacists, as experts on medication use, are uniquely qualified to
212 serve as medication safety leaders. Medication safety leaders articulate the vision and
213 direction for improving the safety of the medication-use system to prevent patient harm.
214 The medication safety leader's role includes responsibility for leadership through direction
215 and prioritization, medication safety expertise, influencing practice change, research, and
216 education. Through analysis of the organization's medication safety data and literature
217 review, the medication safety leader will lead development and implementation of
218 proactive error-prevention strategies and build a culture of safety across the organization.

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SEIZE THE INITIATIVE

**ASHP House of Delegates 2012
June 10 and 12, 2012**

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.

Thomas J. Johnson, *Board Liaison*

Council Members

- Linda S. Tyler, *Chair* (Utah)
- James A. Klauck, *Vice Chair* (Wisconsin)
- Larry W. Buie (North Carolina)
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- Cynthia A. Clegg (Washington)
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- David B. Weetman (Iowa)
- Michael F. Powell, *Section of Pharmacy Practice Managers Liaison* (Nebraska)
- David R. Witmer, *Secretary*

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Policy Recommendations



A. Revenue Cycle Compliance and Management

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

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

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

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

(Note: This policy would supersede ASHP policy 9902.)

Rationale

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

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

Historically, pharmacy departments have great strength in managing supply chain issues. Drug expenditures are typically a significant portion of any hospital's budget. Pharmacy

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

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

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

Background

The Council voted and the Board agreed to recommend replacing ASHP policy 9902 as follows (underline indicates new text; ~~striketrough~~ indicates deletions):

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

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

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

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

~~To encourage pharmacy managers to identify and resolve medication-related billing issues in government health care programs that could cause challenges under fraud and abuse laws; further,~~

~~To encourage pharmacy managers to establish an internal audit system for medication-related services, in conjunction with their corporate compliance programs, in order to meet the requirements of government health care payment policies.~~



B. Prior Authorization Processes

- 1 To advocate that public and private payers work together and in collaboration with
- 2 providers to create standardized and efficient prior authorization processes that
- 3 facilitate communication between patients, providers, and payers prior to therapy;
- 4 result in timely coverage decisions; and do not disrupt patient care.

Rationale

Prior authorization processes vary considerably and are time consuming. The required data, form of documentation required, submission process, and delivery of approval vary among payers. These processes are often not integrated into the patient-care process and require manual documentation and submission. The lack of timely review and approval may result in delay of patient care. The Council believed that ASHP should advocate for greater standardization of prior authorization processes. These processes should effectively facilitate communication among both patients and providers, should be standardized and automated, and should result in timely decisions that do not disrupt patient care.

Background

The Council discussed prior authorization as a part of a broader discussion of compliance and revenue cycle management. The Council believed that inconsistent and inefficient prior authorization processes were having a negative impact on patient care in hospitals and health systems and that ASHP should establish new policy encouraging more efficient and more standardized processes that facilitate effective patient care. The Council recommended and the Board agreed to this new policy.



C. Financial Management Skills

- 1 To foster the systematic and ongoing development of management skills for health-
- 2 system pharmacists in the areas of (1) health-system economics, (2) business plan
- 3 development, (3) financial analysis, (4) pharmacoeconomic analysis, (5) diversified
- 4 pharmacy services, (6) compensation for pharmacists' patient-care services, and (7)
- 5 revenue cycle compliance and management; further,

- 6 To encourage colleges of pharmacy to incorporate these management areas in course
- 7 work and clerkships.

(Note: This policy would supersede ASHP policy 0508.)

Rationale

Revenue cycle compliance and management represent an increasingly important aspect of the business operations of hospitals and health systems. Pharmacy leaders must exert leadership in managing medication-related revenue cycle compliance in order to ensure financial success of the health care enterprise. Pharmacy leaders must develop and maintain knowledge and skills in this area.

Background

The Council recommended and the Board agreed to revise ASHP policy 0508 as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To foster the systematic and ongoing development of management skills for health-system pharmacists in the areas of (1) health-system economics, (2) business plan development, (3) financial analysis, (4) pharmacoeconomic analysis, (5) diversified pharmacy services, ~~and~~ (6) compensation for pharmacists' patient-care services, and (7) revenue cycle compliance and management; further,

To encourage colleges of pharmacy to incorporate these management areas in course work and clerkships.



D. Transitions of Care

- 1 To recognize that continuity of patient care is a vital requirement in the appropriate
- 2 use of medications; further,

- 3 To strongly encourage pharmacists to assume professional responsibility for ensuring
- 4 the continuity of pharmaceutical care as patients move from one setting to another
- 5 (e.g., ambulatory care to inpatient care to home care); further,

- 6 To encourage the development of information systems that facilitate sharing of
- 7 patient-care data across care settings and providers; further,

- 8 To advocate that payers and health systems provide sufficient resources to support
- 9 effective transitions of care; further,

- 10 To encourage the development of strategies to address the gaps in continuity of
- 11 pharmaceutical care.

(Note: This policy would supersede ASHP policy 0301.)

Rationale

Health care reform will have a significant impact on the implementation of new pharmacy practice models. Changes in health care reimbursement will likely result in an increasing focus on the role of pharmacists at the transition of care from the acute care environment to other settings. ASHP policy 0301 will be increasingly important as health systems increase their focus on reducing readmissions, improving patient satisfaction, and effectively educating patients about their medications. It is important that ASHP advocate for improvements in information systems that facilitate sharing of patient information across various care settings. Further alignment of financial incentives and resources that encourage and support patient-care roles of pharmacists in the transition of care are also required.

Background

The Council recommended and the Board approved with amendment revising ASHP policy 0301 as follows (underscore indicates new text):

To recognize that continuity of patient care is a vital requirement in the appropriate use of medications; further,

To strongly encourage pharmacists to assume professional responsibility for ensuring the continuity of pharmaceutical care as patients move from one setting to another (e.g., ambulatory care to inpatient care to home care); further,

To encourage the development of information systems that facilitate sharing of patient-care data across care settings and providers; further,

To advocate that payers and health systems provide sufficient resources to support effective transitions of care; further,

To encourage the development of strategies to address the gaps in continuity of pharmaceutical care.



E. Value-Based Purchasing

- 1 To support value-based purchasing reimbursement models when they are
- 2 appropriately structured to improve health care quality, patient satisfaction, and
- 3 clinical outcomes, and encourage medication error reporting and quality
- 4 improvement; further,
- 5 To encourage pharmacists to actively lead in the design and interdisciplinary
- 6 implementation of medication-related value-based purchasing initiatives.

(Note: This policy would supersede ASHP policy 0708.)

Rationale

[Value-based purchasing](#) is one aspect of a portfolio of health care reform incentives based on pay-for-performance principles. It is currently constructed of 12 clinical outcomes measures and one “measure” of patient experience utilizing the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS). CMS is expanding its Potential Future Measures for Hospital Value-based Purchasing Program to consider the following measures for the [Hospital Value-based Purchasing Program](#):

- Spending per Hospital Patient with Medicare
- Serious Complications and Deaths
- Hospital Acquired Conditions
- Emergency Department Wait Times
- Heart Patients Given a Prescription for Drugs called Statins at Discharge
- Central Line-associated Blood Stream Infection
- Surgical Site Infections
- Immunization for Influenza
- Immunization for Pneumonia
- Temperature Management for Patients after Surgery

ASHP policy 0708 needs to be broadened to include the concepts of value-based purchasing and incorporate the concepts of clinical outcomes and patient satisfaction in addition to quality. ASHP policy should recognize the pharmacist’s leadership role while explicitly acknowledging the interdisciplinary nature of initiatives designed to achieve value-based purchasing measures.

Background

The Council recommended and the Board agreed to amend ASHP policy 0708 as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To support ~~pay for performance~~ value-based purchasing reimbursement models when they are appropriately structured to improve health care quality, patient satisfaction, clinical outcomes, and encourage medication error reporting and quality improvement; further,

~~To oppose pay for performance reimbursement models that do not support an open culture of medication error reporting; further,~~

To encourage pharmacists to actively lead in the design and interdisciplinary implementation of medication-related ~~pay for performance~~ value-based purchasing initiatives.



F. Role of Corporate Pharmacist Leadership in Multifacility Organizations

- 1 To advocate that a pharmacist must be responsible for leadership and have responsibility
- 2 for standardization and integration of pharmacy services in multiple business units across
- 3 the entire pharmacy enterprise of multifacility health systems and integrated delivery
- 4 networks; further,
- 5 To educate health-system administrators about the importance of pharmacy leadership in
- 6 setting system-wide policy regarding the safe and effective use of medications.

Rationale

Data from the 2009 American Hospital Association (AHA) annual survey of hospitals indicates that at the time of the survey, 4406 of 5795 hospitals were part of either a system or a network (there may be some overlap among systems and networks). The rate of mergers and acquisitions has been increasing in the last three years, and it has been estimated that by 2013 the number of networks will be reduced from 2200 to approximately 1000. The health care enterprise is evolving from single hospitals to integrated systems and networks. Leadership of the pharmacy must evolve from a department leader in a single facility to an effective corporate leader of medication use across a wide array of business units, care settings, and organizations. The pharmacy enterprise of the future will be more sophisticated and corporate in its nature. Many important decisions that influence medication-use policy will be made at the level of corporate leadership, and it will be critical that pharmacists provide leadership in this corporate decision-making. The ability to demonstrate financial impact of pharmacy services will be critical and the development and implementation of effective drug-use policy across the enterprise will be crucial to success.

Along with increasing consolidation and integration of health systems, the business model for health care is also evolving. Pharmacy leaders will need to become familiar with

changing business imperatives and align the pharmacy business plan with that of the health system. Planning must integrate at both the strategic and tactical level. Pharmacy needs to be envisioned as a service rather than a department.

Background

The Council recommended and the Board agreed to develop new policy.



G. Pharmacist's Role in Health Care Information Systems

- 1 To strongly advocate key decision-making roles for pharmacists in the planning, selection,
- 2 design, implementation, and maintenance of medication-use information systems,
- 3 electronic health records, computerized provider order entry systems, and e-prescribing
- 4 systems to facilitate clinical decision support, data analysis, and education of users for the
- 5 purpose of ensuring the safe and effective use of medications; further,

- 6 To advocate for incentives to hospitals and health systems for the adoption of patient-
- 7 care technologies; further,

- 8 To recognize that design and maintenance of medication-use information systems is an
- 9 interdisciplinary process that requires ongoing collaboration among many disciplines;
- 10 further,

- 11 To advocate that pharmacists must have accountability for strategic planning and direct
- 12 operational aspects of the medication-use process, including the successful deployment
- 13 of medication-use information systems.

(Note: This policy would supersede ASHP policy 0921.)

Rationale

The Council discussed the evolving nature of health IT and the technology requirements for the pharmacy enterprise. The Council believed that current ASHP policy did not clearly describe the successful design and use of technology that supports the medication-use process as an interdisciplinary effort and voted to amend ASHP policy 0921 to reflect the interdisciplinary nature of the medication-use process that requires collaboration in design, implementation, and maintenance. The Council also believed that it was important that pharmacists have accountability for the medication-use process, including the successful deployment of medication-use information systems.

Background

The Council recommended and the Board agreed to amend ASHP policy 0921 as follows (underline indicates new text; ~~strike through~~ indicates deletions):

To strongly advocate key decision-making roles for pharmacists in the planning, selection, design, implementation, and maintenance of pharmacy medication-use

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; further,

To recognize that design and maintenance of medication-use information systems is an interdisciplinary process that requires ongoing collaboration among many disciplines; further,

To advocate that pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use information systems.



H. Clinical Decision Support

- 1 To advocate for the development of clinical decision support (CDS) systems that are
- 2 proven to improve medication-use outcomes and that include the following
- 3 capabilities: (1) alerts, notifications, and summary data views based on (a) a rich set of
- 4 patient-specific data, (b) standardized, evidence-based medication-use best practices,
- 5 and (c) identifiable patterns in medication-use data in the electronic health record; (2)
- 6 audit trails of all CDS alerts, notifications, and follow-up activity; (3) structured clinical
- 7 documentation functionality linked to individual CDS alerts and notifications; and (4)
- 8 highly accessible and detailed management reporting capabilities that facilitate
- 9 assessment of the quality and completeness of CDS responses and the effects of CDS
- 10 on patient outcomes.

Rationale

The Council discussed the technology requirements of the pharmacy enterprise and ASHP policies related to technology. The Council believed that one area where a gap in ASHP policy existed was in the area of clinical decision support. Current clinical decision support systems do not provide the functionality that is required in the future practice model that is envisioned by participants at the [Pharmacy Practice Model Initiative](#) (PPMI) Summit. The Council believed that ASHP should advocate for improvements in clinical decision support systems that provide actionable data analytics and support the medication-use process.

Background

The Council and the Section of Pharmacy Informatics and Technology recommended new policy on clinical decision support, and the Board approved the policy with amendment.

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.)

- [Standard Drug Administration Schedules](#) (0707)
- [Staffing for Safe and Effective Patient Care](#) (0201)
- [Performance Improvement](#) (0202)
- [Reimbursement for Unlabeled Uses of FDA-Approved Drug Products](#) (0206)

Other Council Activity

Revenue Cycle Compliance and Management

The Council voted

To develop an ASHP statement on revenue cycle compliance and management.

In addition to recommending new ASHP policy on this subject, the Council voted to develop a formal policy statement on this subject. The Council believed it was important to establish ASHP policy on this issue as noted earlier, but also believed there would be value in ASHP developing a clear policy position on this subject that more clearly articulates the importance of pharmacist participation by providing a more detailed description of the process and role of the pharmacist.

Pharmacists Credentialing and Privileging

The Council voted

To develop ASHP guidelines on credentialing and privileging.

The Council discussed the assessment and documentation of pharmacists' scope of practice. The role of pharmacists is changing as pharmacists become more accountable for patient care. The Council reviewed several papers published in *AJHP* describing the use of credentialing and privileging of pharmacists, the results of the PPMI Summit, a position paper published by the Council on Credentialing in Pharmacy (CCP), and the new business item submitted by the Section of Clinical Specialists and Scientists that was approved at the ASHP House of Delegates.

The Council believed that it would be increasingly important that pharmacists participate in some form of credentialing and privileging process. Physicians and administrators are familiar with board certification and with credentialing and privileging, and the adoption of such models serves to validate pharmacists' knowledge and skills and advance their practices. Several Council members noted that pharmacists in their organizations currently participate in a credentialing and privileging process or that such a process was currently being investigated. It was also noted that these processes varied greatly among organizations and there would be

value in ASHP defining more clearly the core elements of such a process. In some organizations, pharmacists were credentialed by the medical staff committee, while in others the credentialing process for pharmacists occurred through the pharmacy. The Council believed that the pharmacy credentialing and privileging process should be under the oversight of the pharmacy but should be integrated with the medical staff credentialing process. The Council also noted that credentialing and privileging processes for pharmacists may be more important in the future as health systems expand the role of pharmacists in ambulatory practice environments.

The Council voted to develop ASHP guidelines on credentialing and privileging. The Council believed that these guidelines should advocate that credentialing for pharmacists be pharmacist-led but should integrate with medical staff credentialing programs and include medical staff review. The position should encourage credentialing and privileging for advanced roles, especially in the area of collaborative practice. The guidelines should also define standardized elements of a pharmacist credentialing and privileging process in hospitals and health systems. The Council also believed that faculty who practice in hospitals or health systems should also participate in the organization's credentialing and privileging process.

The Council also discussed the New Business Item from the Section of Clinical Specialists and Scientists. The Council was supportive of all elements of the New Business Item and also supported the concept that a vision for the future should be that specialty training would at some point become a prerequisite for board certification. The Council recognized that there remains confusion in the profession about the development of specialties and the difference between specialties and other types of certifications and encouraged ASHP and the Section to educate members. The Council also acknowledged that it would be many years before the profession would reach a point where pharmacy specialists would be both trained and certified and recognized that the profession would need to plan for a transition that did not exclude talented pharmacy professionals who are already engaged in specialty practice.

Effective Use of Consultants

The Council voted

To develop ASHP guidelines on the effective use of consultants within the pharmacy enterprise.

Based on a recommendation from the House of Delegates, the Council discussed the effective use of consultants. The Council noted that there are many different types of consultants that may be engaged by the health system that may provide advice regarding the pharmacy enterprise. In addition to finance and business consultants, these may include IT experts, human resource specialists, and quality improvement consultants. The effective use of consultants can assist the pharmacy enterprise in advancing patient care. This is especially true as the complexity of the medication-use process increases and expertise outside of pharmacy is necessary to implement systems or technology. The Council noted that most of the problems stemming from the use of consultants occurred when financial and business consultants are hired without input from the pharmacy. In many cases, these consultants are engaged to identify cost reductions. In these circumstances, the pharmacy is often not involved in defining

the scope of work or reviewing the qualifications of the consultant relative to the scope of work. The results of the consultants' work also often report benchmarks relative to other peer groups, but the pharmacy director is not provided with peer group data necessary to assess the validity of the peer group. The Council believed it would be valuable for ASHP to develop guidelines that clearly define the key elements of an effective consulting relationship, including expertise relative to the scope of work, clearly defined scope of work, clear and transparent objectives, and access to peer group data and metrics.

The Council also again discussed the appropriate use of workload and productivity measures for the pharmacy enterprise. The Council acknowledged the work of the Section of Pharmacy Practice Managers and ASHP in developing useful publications and providing education on this topic. However, the Council believed that this should remain a high priority for ASHP. Council members noted that pharmacy managers will increasingly be required to establish valid metrics related to pharmacy's organization performance. ASHP must take a leadership role in establishing these metrics and educating members about how to effectively measure and apply them. Council members noted that there is a need to establish metrics related to the care pharmacists provide, to pharmacists' functions that relate to patient satisfaction, and to those that affect readmissions. Council members also believed that such metrics will need to be simple and easy to understand. Health-system executives are not going to place their trust in measures that are complex and difficult to understand. ASHP should also seek opportunities to partner with American College of Healthcare Executives (ACHE) in the development of effective measures.

ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive

The Council voted

To revise the [ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive](#).

As the Council discussed a number of topics it identified skills that are not currently identified in the *ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive*. These included responsibilities for business planning, managing merger and integration of new pharmacy business units, role in integrating pharmacy strategic and tactical planning with the business plans of the enterprise, knowledge of corporate decision- and policymaking, alignment of business units across the continuum of care, contracting, and revenue cycle management and compliance. The Council believed that the statement should be revised to incorporate these skills, as they will increasingly be required in large systems and integrated delivery networks.

Principles of Managed Care

The Council voted

To compile further background information and review [ASHP policy 0709, Principles of Managed Care](#), at a future meeting of the Council.

The Council reviewed policy 0709 as a part of sunset review of policies and believed the policy should be revised but wanted to gather more information prior to undertaking a revision. The Council voted to place the topic on the agenda for next year's Council and asked staff to gather further background relating to this policy.

Product Reimbursement and Pharmacist Compensation

The Council voted

To compile further background information and review [ASHP policy 0207, Product Reimbursement and Pharmacist Compensation](#), at a future meeting of the Council.

The Council reviewed policy 0207 as a part of sunset review of policies and believed the policy should be revised but wanted to gather more information prior to undertaking a revision. The Council voted to place the topic on the agenda for next year's Council and asked staff to gather further background relating to this policy.

Development of Ambulatory Pharmacy Programs in Health Systems

The Council discussed the role of the pharmacy enterprise in caring for patients in ambulatory care settings. As CMS implements the Affordable Health Care Act and various components included under the law, hospitals and health systems are becoming increasingly accountable for health care quality. With this increasing accountability, hospitals and health systems are increasingly assuming responsibility for the outcomes of ambulatory patients. The development of [accountable care organizations](#) (ACOs) and medical homes (MHs) is also driving more interest in ambulatory care among health systems. This will create opportunities for expansion of ambulatory pharmacy services to ensure the best possible outcomes for their patients. Ambulatory patients can receive pharmaceutical services in a number of health-system settings, including freestanding pharmacies, ambulatory care clinics, hospital outpatient departments, assisted living centers, infusion centers, and physician offices. Hospital and health-system pharmacy leaders should assertively plan for the expansion of pharmacy services that provide medications to ensure continuity of care, improve medication adherence, and avoid medication misadventures, thereby minimizing hospital readmissions.

The Council also noted that these changes are also affecting other segments of pharmacy practice. Hospital pharmacy departments should also be aware of the impact of the new 340B Drug Pricing Program rules that allow a single hospital site to contract with multiple contract pharmacies to dispense 340B drugs. Chain drug stores are approaching hospitals and health systems to contract with the hospitals to dispense 340B drugs. Some health systems have entered these contracts without the input or involvement of the pharmacy department. While these contract pharmacy arrangements may provide increased access to 340B drugs for patients, they also allow both pharmacy market capture and 340B savings capture by the chain pharmacies. The impact of these contract pharmacy arrangements on both the 340B Drug Pricing Program as well as outpatient pharmacy services provided by hospitals and health systems should be examined.

The Council believed that ASHP should develop education, tools, and resources to assist members in responding to this changing environment. While the Council believed that PPMI provides a road map, there is a need to more clearly link PPMI to an ambulatory care strategy and define clearly the roles of pharmacists in ambulatory care. Changing economic models for health systems will result in an increased focus on ambulatory care and pharmacy will need to align both a practice model and business model that effectively deploys pharmacists to improve outcomes and quality, reduce costs, and reduce readmissions of ambulatory patients.

Contemporary Roles of Pharmacy Technicians in the Pharmacy Enterprise

The Council discussed the contemporary roles of pharmacy technicians and reviewed results of the PPMI Summit. The Council supported the consensus of the Summit and agreed that pharmacy technicians should be licensed. The Council reviewed [ASHP policy 0702, Pharmacy Technician Training](#), and [policy 8610, Pharmacy Technicians](#), and suggested that these policies should be strengthened. The Council noted that tech-check-tech is already permitted in a number of states, and that technicians working for the Department of Defense function very differently than those in the civilian sector and bear primary responsibility for drug distribution. The Council believed that economic pressures on health care will require pharmacy to adapt and utilize technicians to a much greater extent in order to achieve the vision of the PPMI summit.

The Council believed that ASHP should focus more effort on developing technician education. There are currently too few accredited training programs. ASHP should encourage the development of more accredited training. There is also a need for education and training of technicians beyond the basic requirements for accredited training. ASHP should develop resources to assist hospitals and health systems to train technicians in more advanced support roles such as managing investigational drugs, managing patient assistance programs, chemotherapy preparation, and others.

Factors Influencing Medication Complexity Index

An outgrowth of the PPMI Summit was an effort to develop a medication complexity index. The Council was asked to review available literature from pharmacy, nursing, and other disciplines with the goal of recommending factors the expert panel should consider. An expert panel, convened by ASHP and the ASHP Foundation, has been formed and charged with development of a Patient Medication Complexity Index that can be used by hospitals and health systems that are committed to advancing their pharmacy practice models. This complexity index will be a tool that supports allocation and/or reallocation of pharmacist-provided drug therapy management services to individual patients and populations of patients in both the inpatient and health system-based outpatient settings.

Nursing has utilized patient acuity modeling to determine staffing for some time, and commercial products are available to assist in the assignment of nursing resources. These models have allowed nursing to adjust scheduling continuously based upon volume and acuity. Some hospitals have begun to utilize such solutions in other departments. The Council noted that the complexity of medication therapy is affected by numerous factors, including the therapeutics of the drug therapy, the number of drugs utilized, the number of concomitant

disease states, specific pharmacodynamic variables related to drug metabolism and elimination, the mode of drug delivery, the rate of disease progression, and frequency of drug therapy adjustments for certain care units or patient populations, among others.

The Council believed that ASHP and pharmacy directors need to envision a tool that could be utilized more prospectively to assign or reallocate pharmacists based on patient needs and not simply as a tool that could be used to determine the number of pharmacists needed and justify new positions. Such a tool could allow managers to focus pharmacists' time where pharmacy can most provide value. The Council noted that pharmacy has traditionally thought of assigning a full-time equivalent (FTE) to a unit, but should be thinking of deploying pharmacists as both fixed and variable resources. Pharmacists could be deployed to high-risk patients across the enterprise rather than assigned to a specific patient-care unit. This concept could be expanded even further via telepharmacy solutions to allow pharmacy specialists to serve complex patients across an entire system or network. Individual pharmacists could also be shifted from one patient-care unit to another based upon the complexity and patient needs.

The Council noted that such a system would need to be simple, highly automated, and integrated with the health system's health IT infrastructure. It will be important to plan for a tool that facilitates the deployment of pharmacists for both acute care as well as ambulatory patients. The Council also noted that the use of such a tool would likely be quite different in a very small facility compared to a large tertiary referral center. The Council believed that the effective development of such a tool could support the development of more effective benchmarking.

Interface of Health Care Reform and Practice Models

The Council discussed the impact of health care reform efforts and economic pressures on successful implementation of the PPMI. There is great uncertainty in many business sectors right now and health care is among them. Hospitals and health systems are evaluating the impact of health care reform and changing reimbursement models on their business. Some hospital administrators are questioning the future of accountable care organizations, while others are embracing the concept. The pace of consolidations and mergers has continued to increase and most urban markets now have no more than three health systems. Health systems are developing more corporate structures and cultures. Many health systems are currently downsizing staffing in anticipation of lower reimbursements.

Regardless of the current uncertainty it appears likely that hospital and health care reimbursements will change and that while there may be further change over time some trends will continue. There will likely be continuing pressure to reduce the cost of health care, and health systems are likely to face increasing pressure to reduce costs, improve quality, improve patient satisfaction, and reduce readmissions. The Council believed that it will be critical for pharmacy leaders to understand how these changes are affecting the economic outcomes of the health care enterprise and develop new business plans for the pharmacy enterprise that clearly define pharmacy's value in terms of revenue and in terms of achieving value-based purchasing objectives that drive revenues. Further, pharmacy will need to define and measure its impact on patient care and on organizational objectives. There will be a need to reallocate resources including expanded use of technicians and technology, reallocation to ambulatory

care and managing transitions of care, and changes to models for training students and residents.

The Council also discussed [ASHP policy 0227, Pharmacist's Responsibility for Patient Safety](#). The Council believed that this policy did a good job of defining the pharmacist's responsibilities but should be strengthened to include responsibilities of the pharmacy department. The policy should also encourage the development and implementation of training pharmacists in the application of tools and techniques such as root cause analysis. The Council recommended that the Council on Pharmacy Practice review the policy next year for possible revision.

The Council encouraged ASHP to develop education and resources to assist pharmacists in making these transitions. Areas of need include patient adherence, customer service and patient satisfaction, business planning, managing change, efficiency and process management, and strategies to link PPMI to business plans.

Workload and Productivity Measures

Based on a recommendation from the House of Delegates, the Council discussed the need for ASHP-endorsed workload and productivity measures. The Council has discussed concerns with workload and productivity measurement at several past meetings and acknowledged that ASHP and the SPPM have developed useful publications and educational offerings to assist members, but also agreed that there is a need for ASHP to take more formal leadership in developing uniform measures. The Council noted that administrators will not accept the excuse that pharmacy is different and will increasingly require pharmacy directors to compare their performance with that of other organizations. The Council acknowledged that this will not be an easy undertaking, but also believed strongly that there is a need to develop measures even if they are not perfect. Council members noted that administrators want simple and easy-to-understand measures. ASHP should avoid the approach of trying to achieve perfection and should focus on incremental improvement. The Council believed the use of a balanced scorecard approach could be useful and that the development of a medication acuity index may also be part of the solution. The Council also suggested that ASHP engage administrator organizations and consider a partnership with groups such as ACHE.



SEIZE THE INITIATIVE

ASHP House of Delegates 2012
June 10 and 12, 2012

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.

Larry C. Clark, *Board Liaison*

Council Members

- Brian D. Hodgkins, *Chair* (California)
- Christopher Betz, *Vice Chair* (Kentucky)
- Donna J. Field (Washington)
- Ryan A. Forrey (Ohio)
- Kristine P. Gullickson (Minnesota)
- Arlene M. Iglar (Wisconsin)
- Nishaminy Kasbekar (Pennsylvania)
- Lindsey R. Kelley (Pennsylvania)
- Rachel M. Krueger, *New Practitioner* (Maryland)
- Suzanne R. Schrater (Kansas)
- Melinda C. Stanton, *Student* (Ohio)
- Majid R. Tanas (Oregon)
- Bona E. Benjamin, *Secretary*

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(Click on title to view section)

Policy Recommendations



A. Pharmacist Prescribing in Interdisciplinary Patient Care

- 1 To define pharmacist prescribing as follows: the selection, initiation, monitoring, and
- 2 adjustment of medication therapy pursuant to diagnosis of a medical disease or
- 3 condition; further,

- 4 To advocate that health care organizations establish credentialing and privileging
- 5 processes that delineate the scope of pharmacist prescribing within the hospital or
- 6 health system and to ensure that pharmacists who prescribe are competent and
- 7 qualified to do so.

Rationale

The [Pharmacy Practice Model Initiative](#) (PPMI) Summit recommended that “[t]hrough credentialing and privileging processes, pharmacists should include in their scope of practice prescribing as part of the collaborative practice team.” (Recommendation B14) With the demand for health care growing as the nation ages and increasing concern about the shortage of primary care providers, expanding the pharmacist’s role will contribute to the overall capacity of the health care workforce to meet patients’ primary health care needs.

As pharmacist prescribing is an innovative concept, a clear, concise definition of what it means and does not mean has yet to be established. Unlike physician prescribing, which is commonly understood to be the diagnosis and treatment of diseases and conditions, various terms are currently used to describe pharmacists’ medication ordering activities, such as prescriptive authority, collaborative practice, and collaborative drug therapy management (CDTM). These differ in definition and interpretation, depending on state scope of practice laws and other factors. A standard definition of pharmacist prescribing will facilitate future discussions on the role of pharmacists in interdisciplinary health care, help delineate health care team roles, enhance collaborative patient care, and clarify the meaning of pharmacist prescribing for other health care providers.

In the proposed definition, pharmacist prescribing differs from that by other authorized prescribers and from medication therapy management (MTM) and CDTM in three significant aspects. First, prescribing by pharmacists requires active participation in the patient’s health care team or active engagement and coordination with other individual practitioners responsible for the patient’s care. Second, pharmacist prescribing must take place in concert with assessment, diagnosis, and other clinical findings contributed by the patient’s other care providers, and changes in the patient’s medication therapy must be communicated to these individuals in a readily available and timely manner. Third, pharmacists who prescribe are accountable to patients and to the health care team for exercising professional judgment in pharmacotherapy and medication-use decision-making according to their defined scope of

services, as well as for the outcomes of those services. While many pharmacists may currently order medications under protocols for MTM or CDTM, prescribing entails a higher degree of autonomy and is a role for advanced practitioners with demonstrated competency and expertise.

Although clinical pharmacy specialists practicing in highly focused clinical areas such as oncology and transplant often become skilled at diagnosing and treating symptoms in their respective patient populations, and pharmacists are prepared and qualified to interpret medication-related clinical laboratory results, the education and training pharmacists receive in physical assessment does not prepare or qualify them to be diagnosticians. Pharmacist prescribing may therefore be described as interdependent, but under this interdependent model, review, approval, and co-signature of pharmacist-prescribed medications by a licensed independent prescriber should be unnecessary, if pharmacists are in fact accountable for medication therapy outcomes. ASHP policy supports pharmacist authority in matters of medication therapy, autonomy in exercising professional judgment, and accountability for medication therapy outcomes. Patients are best served, however, when the expertise of pharmacists is applied to therapeutic use of medicines after definitive diagnosis indicates that medicines are the appropriate therapy.

The [American Medical Association](#) and the [American Academy of Family Physicians](#) have publicly and staunchly opposed any expansion of pharmacist scope of practice perceived to encroach on the practice of medicine. Pharmacist prescribing is implicit to interdisciplinary care delivery, however. Independent drug therapy decision-making by pharmacists in hospitals is already common. It is often accepted and even expected by physicians. Physicians participating in multidisciplinary teams with pharmacists come to rely on their knowledge and see an opportunity to free themselves from tasks that can be done by another professional with demonstrated competency and expertise. Pharmacists in specialty practices such as anticoagulation management, solid organ transplant, and nutrition support have long functioned in roles in which near-independent authority to manage drug therapy has resulted in improved outcomes. In settings such as the Indian Health Service and Veterans Affairs health systems, where access to a primary care provider is limited, care provided by pharmacists with prescribing authority has demonstrated the benefits of this model.

Most hospitals authorize pharmacists to manage drug therapy by enacting Pharmacy and Therapeutics Committee policies that require use of an approved medical staff protocol and physician oversight for pharmacist-initiated orders. In practice, however, pharmacists often manage patients' clinical needs that cannot be appropriately treated per protocol with minimal physician oversight. Depending on the patient, medication, and degree of trust, physicians may co-sign such orders with only cursory review. To the extent allowed by hospital policy, physicians often delegate therapeutic decision-making to pharmacists, secure in the trust developed through established professional relationships and shared experiences in successfully dealing with challenging clinical situations, rather than through formal collaborative practice agreements. Common examples of de facto pharmacist prescribing include independently managing symptoms and side effects in oncology patients, identifying and resolving drug-induced disease or problems, managing anticoagulant therapy for patients whose clinical status falls outside protocol-specified parameters, and responding to general directives to simply "fix the problem" when medication therapy is indicated.

Credentialing by individual health care organizations is a natural selection process for determining who is authorized to prescribe that avoids distinguishing pharmacists by practice setting and allows more latitude in scope of practice. The credentialing procedures to establish pharmacists' competency to prescribe must ensure that patients receive treatment from highly qualified caregivers. In addition to verifying appropriate education, licensure, and certification, the process should include

- the same transparency and rigor applied to other prescribers,
- criteria used to measure patient care quality, and
- peer review by pharmacists and others who are authorized to prescribe.

Health care organizations should use privileging methods that establish the scope of practice and clinical services that pharmacists are authorized to provide commensurate with their demonstrated competency within an area or areas of clinical expertise. Pharmacists practicing in hospitals and health systems do not have or need privileges, such as admitting, that are not related to medication use.

Finally, interdisciplinary health professional training programs should incorporate the concept of pharmacist prescribing in a standard way.

Background

The Council voted and the Board agreed to establish a definition of pharmacist prescribing that can be used to promote common understanding of this term in the health care community. Acknowledging inevitable opposition by other licensed independent prescribers, the Council recommended a number of tactics ASHP should consider when implementing the policy:

- Establish a clear definition with supporting rationale.
- Explore and resolve concerns of other disciplines about encroachment into the practice of medicine.
- Identify the potential for pharmacists to extend the capacity of the primary care provider workforce by relieving primary care providers of unnecessary tasks, reducing medication-related adverse events, and improving therapeutic outcomes.
- Encourage and support expanded state scope of practice acts.
- Develop messaging to address financial implications for physicians if they are concerned about reimbursement restructuring.
- Emphasize the collaborative nature of pharmacist prescribing and its benefits to patients, prescribers, and other health care workers using data on the dwindling health care workforce, particularly primary health care providers, and the anticipated increase of patients due to health care reform and the aging baby boomer population.
- Assess, analyze, and develop strategies to resolve ethical and legal issues.
- Educate pharmacists on the implications of an advanced practice that includes prescribing.

In light of regulatory, reimbursement, and other changes that must first take place, the Council predicted that implementation will occur in phases and the pharmacist's prescribing role will continuously evolve until state practice acts are changed, liability issues are defined, and ethical concerns are resolved. The Council acknowledged a number of regulatory and scope of practice

issues that may present a barrier to implementing a pharmacist prescribing policy. While few states have scope of practice acts that allow pharmacists to independently prescribe, a number of state boards have initiated discussions of this topic, and at least one state, Washington, is currently developing regulations for pharmacist prescribing within a collaborative practice model. Because these topics fall under the purview of the Council on Public Policy, the Council focused instead on the importance of licensing, privileging, and credentialing procedures by hospitals for pharmacists who prescribe.



B. Pharmacist's Role in Accountable Care Organizations

- 1 To recognize that pharmacist participation in collaborative health care teams
- 2 improves outcomes from medication use and lowers costs; further,

- 3 To advocate to health policymakers, payers, and other stakeholders for the inclusion
- 4 of pharmacists as health care providers within accountable care organizations (ACOs)
- 5 and other models of integrated health care delivery; further,

- 6 To advocate that pharmacist-provided care (including care coordination services) be
- 7 appropriately recognized in reimbursement models for ACOs; further,

- 8 To advocate that pharmacists be included as health care providers in demonstration
- 9 projects for ACOs; further,

- 10 To encourage comparative effectiveness research and measurement of key outcomes
- 11 (e.g., clinical, economic, quality, access) for pharmacist services in ACOs; further,

- 12 To encourage pharmacy leaders to develop strategic plans for positioning pharmacists
- 13 in key roles within ACOs.

Rationale

The Affordable Care Act of 2009 encourages the formation of [accountable care organizations](#) (ACOs). Similar in concept to health maintenance organizations, these entities consist of alliances between physicians, other health care providers, and hospitals that provide comprehensive and coordinated health care to a population of patients. ACOs emphasize primary and preventive care, are provider-led, and receive reimbursement linked to increasing health care quality and lowering per capita costs. The ACO model is based on the premise that care coordinated in this manner and incentivized by a shared-risk reimbursement model will improve health care quality and slow the growth of health care spending. One significant deterrent to pharmacist participation in the fee-for-service care model, lack of provider status, is less of a barrier in the ACO model because reimbursement is tied to quality and reduced costs rather than specific services.

Integrated systems present an important opportunity for pharmacists to demonstrate their value to the quality of care. Pharmacists could contribute to the success of ACOs by providing the following patient care services:

- Developing, implementing, and monitoring patient-specific, evidence-based drug therapy as an active participant in team-based care.
- Improving transitions in care with coordinated MTM services for patients in the hospital as well as post-discharge in ambulatory clinics and physician practices.
- Monitoring the therapy of patients with multiple chronic conditions or complex medication regimens.
- Preventing and managing adverse drug events.

Although a number of ACOs have already evolved from existing disease management and medical home programs, not much is known about the elements of success for ACOs, and implementation is likely to be challenging. To establish these elements of success, pharmacists will need to be included in ACO demonstration projects and pharmacist services will need to be the subject of research on ACO effectiveness.

As pharmacists assume the expanded roles outlined in the PPMI recommendations, pharmacy leaders should use their expertise to explore innovative strategies to meet the broader goals of ACOs. This payment model is an opportunity to demonstrate how pharmacists can help these organizations reach clinical and financial performance targets set by the Centers for Medicare & Medicaid Services (CMS), i.e., improved patient results and lower health care costs. Pharmacy managers and other pharmacy leaders should prepare now to participate in emerging ACOs by developing strategic plans for positioning pharmacists in roles where their expertise can be best applied to these goals.

Background

Although a number of ACOs have already evolved from existing disease management and medical home programs, the Council noted that implementation is likely to be challenging and considered whether policy development should be deferred until more is known about the elements of success for ACOs. [Final regulations for ACOs](#) were not released until October 2011, after the Council's meeting, but the Council concluded that ASHP policy is needed now to establish the role of pharmacists in ACOs and demonstrate ways pharmacists can contribute to quality of care while lowering costs.



C. Pharmacist's Role in Team-Based Care

- 1 To recognize that pharmacist participation in interdisciplinary health care teams as
- 2 the medication-use expert increases the capacity and efficiency of teams for
- 3 delivering high-quality care; further,

- 4 To assert that pharmacists are responsible for coordinating the care they provide with
- 5 that provided by other members of the health care team and are accountable to the
- 6 patient and to the health care team for the outcomes of that care; further,

- 7 To urge pharmacists on health care teams to collaborate with other team members in
- 8 establishing quality measures for care provided by those teams.

Rationale

The PPMI Summit recommendations are based on a growing consensus among health care providers and payers that patient-centered care by a collaborative team is the optimal model of care. A collaborative care model provides pharmacists with an opportunity to contribute their expertise in medication use to improving patient outcomes.

The pharmacy profession appears to be struggling, however, with implementation of this care model. Not unexpectedly, states appear to vary widely in the way the “team-based care” PPMI recommendations are interpreted and applied. Therefore, states currently in the process of rewriting practice acts have been challenged to find guidance on the fundamental roles and responsibilities of pharmacists in various care settings. This policy recommendation builds on concepts in [ASHP policy 1114, Pharmacist Accountability for Patient Outcomes](#); sets the expectation for other providers that teams with pharmacists will improve the quality, safety, and efficiency of care; and supports advocacy to the broader health care community on the value of care delivery by teams that include pharmacists.

Background

ASHP support for pharmacist participation in interdisciplinary care teams is longstanding. ASHP policy positions, statements, and guidelines support pharmacist participation on the interdisciplinary primary care team, on teams in hospice, and in other care settings as a means of ensuring safe and effective use of medications. In addition, ASHP participates in the Hospital Care Collaborative, an ongoing initiative in collaboration with the Society of Hospital Medicine and others that is aimed at developing and promoting successful models where care is delivered by an interdisciplinary team.

Council members suggested that additional detailed practice guidance is required to unify the profession's approach to team-based care. They recommended development of an ASHP statement or guidelines that address such topics as how teams operate in various care settings, how communication determines team success, the use of national guidelines and core

measures, how to adapt the team or its services to meet patient needs, and using measures of team performance for continuous improvement. The Council emphasized the importance of these data if pharmacists are to continue to be relevant in light of a future health care delivery system that emphasizes coordinated care that is accessible, effective, less expensive, and safer.



D. ASHP Statement on the Pharmacist's Role in Medication Reconciliation

- 1 To approve the *ASHP Statement on the Pharmacist's Role in Medication Reconciliation* ([Appendix](#)).

Background

In 2010, the Council recommended revising ASHP policy 0620, Pharmacists' Role in Medication Reconciliation. After debating and approving the revised policy ([ASHP policy 1117, Pharmacists' Role in Medication Reconciliation](#)), several House delegates recommended development of a statement to more thoroughly delineate ASHP policy on the roles pharmacists should play in medication reconciliation. A statement was subsequently drafted, and the Council reviewed the draft at its September 2011 meeting. The statement was revised to reflect the Council discussion, and the resulting draft was sent for peer review in December 2011. The draft was revised in response to the comments of more than 25 ASHP members as well as representatives of the Academy of Managed Care Pharmacy, the American College of Physicians, and the Canadian Society for Hospital Pharmacists.



E. New and Emerging Medication Ordering and Distribution Systems

- 1 To discontinue ASHP policy 0522, which reads:
 - 2 To support the use of new and emerging medication ordering and distribution
 - 3 systems (e.g., via the World Wide Web) when such systems (1) enable
 - 4 pharmacists to provide patient care services, (2) ensure that patients will not
 - 5 receive improperly labeled and packaged, deteriorated, outdated, counterfeit,
 - 6 or non-FDA-approved drug products, (3) provide appropriate relationships
 - 7 among an authorized prescriber, pharmacist, and patient, (4) enhance the
 - 8 continuity of patient care, (5) support the pharmacist's role as a patient care
 - 9 advocate, and (6) provide for data security and confidentiality.

Background

As part of sunset review, the Council reviewed policy 0522 and noted that Plank 3 of the [ASHP Leadership Agenda](#), Pharmacist Leadership in Health Information Technology, will likely

accomplish much of the intent of this policy. The Council also noted that automated medication distribution systems are adequately addressed in a number of existing ASHP technology policies.



F. Role of Pharmacists in Sports Pharmacy and Doping Control

- 1 To discontinue ASHP policy 0710, which reads:
 - 2 To encourage pharmacists to engage in community outreach efforts to provide
 - 3 education to athletes on the risks associated with the use of performance-
 - 4 enhancing drugs; further,
 - 5 To encourage pharmacists to advise athletic authorities and athletes on
 - 6 medications that are prohibited in competition; further,
 - 7 To advocate for the role of the pharmacist in all aspects of sports pharmacy
 - 8 and doping control.

Background

As part of sunset review, the Council reviewed policy 0710 and concluded that the policy is no longer needed due to stricter regulations and testing for drug abuse in sports.



G. Pharmacist's Responsibility for Patient Safety

- 1 To discontinue ASHP policy 0227, which reads:
 - 2 To affirm that individual pharmacists have a professional responsibility to
 - 3 ensure patient safety through the use of proven interventions and best
 - 4 practices; further,
 - 5 To affirm that employee performance measurement and evaluation systems
 - 6 should incorporate measures that support and encourage a focus on patient
 - 7 safety by pharmacists.

Background

As part of sunset review, the Council reviewed policy 0227 and determined that the concepts in this policy are adequately addressed by ASHP policy 1114, Pharmacist Accountability for Patient Outcomes, which reads:

To affirm that pharmacists are obligated by their covenantal relationship with patients to ensure that medication use is safe and effective; further,

To declare that pharmacists, pursuant to their authority over a specialized body of knowledge, are autonomous in exercising their professional judgment and accountable as professionals and health care team members for safe and effective medication therapy outcomes; further,

To encourage pharmacists to define practices and associated measures of effectiveness that support their accountability for patient outcomes; further,

To promote pharmacist accountability as a fundamental component of pharmacy practice to other health care professionals, standards-setting and regulatory organizations, and 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.)

- [Electronic Health and Business Technology and Services](#) (0712)
- [Appropriate Dosing of Medications in Patient Populations with Unique Needs](#) (0228)
- [Pharmacist's Role in Drug Procurement, Distribution, Surveillance, and Control](#) (0232)
- [Interventions to Reduce HIV Risk Behavior in Intravenous Drug Users](#) (9711)
- [Primary and Preventive Care](#) (9407)
- [Expiration Dating of Pharmaceutical Products](#) (9309)
- [Tamper-Evident Packaging on Topical Products](#) (9211)
- [Nondiscriminatory Pharmaceutical Care](#) (9006)
- [Elimination of Apothecary System](#) (8613)
- [ASHP Statement on the Role of Health-System Pharmacists in Public Health](#)
- [ASHP Statement on Racial and Ethnic Disparities in Health Care](#)
- [ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling](#)
- [Principles of a Sound Drug Formulary System](#) (Endorsed)

Other Council Activity

Pediatric Dosage Forms

The Council voted to defer sunset review of [ASHP policy 9707, Pediatric Dosage Forms of Drug Products](#). The Council requested a report regarding implementation of the policy in order to determine whether the intent has been fully met and will vote by mail ballot.

Ethical Considerations for Patient Prioritization During Drug Shortages

The Council determined that the current critical status of drug shortages requires ethical guidance for pharmacist decision-making regarding patient care when critical medications are scarce or unavailable. Drug shortages have increased at an alarming rate over the last five years and show no sign of declining in the foreseeable future.

Pharmacists play an integral role in communicating drug supply status to the clinical staff and medication-use policy committees in their organizations. Pharmacists also provide expertise in developing prioritization criteria to conserve scarce drug supplies, including recommendations for alternative agents and dose modification.

A number of unresolved ethical issues were raised by the Council, and members recommended that ASHP solicit a bioethicist's expert opinion regarding these issues and publish a comprehensive review of ethical considerations for managing drug shortages in *AJHP*.

ASHP Statement on Professionalism

The Council recommended revising the [ASHP Statement on Professionalism](#) in order to incorporate recommendations from the PPMI Summit and [ASHP policy 1114, Pharmacist Accountability for Patient Outcomes](#).

Shared Accountability Between Pharmacists and Technicians

The Council discussed PPMI Summit recommendations that identify new and expanded roles for technicians in order to provide the practitioner's perspective to the Council on Public Policy's consideration of professional policy on this issue. The Council considered the implications of an expanded technician role that includes greater responsibility, critical thinking, and independent decision-making with regard to operational matters. Council members cited examples of complex technician responsibilities that might significantly advance the practice of pharmacy, such as technical workforce supervision, technology management, and participation in medication reconciliation. Council members offered the following perspectives to the Council on Public Policy.

- Highly skilled, competent technicians are essential if the profession of pharmacy is to advance.
- ASHP should set high standards for technician competence and accountability for the quality of their work.
- Technicians will perform critical, complex, highly technical job responsibilities.

- Technicians should have decision-making authority consistent with these responsibilities.
- Technicians, like any other health care worker, have a fundamental accountability to the patient for acting in a safe and responsible manner in performance of their duties.

The Council's full comments and recommended language on training were forwarded to the Council on Education and Workforce Development for incorporation into its policy on the topic. Recommended policy language on technician accountability and scope of responsibility was forwarded to the Council on Public Policy for evaluation and possible incorporation into a proposed statement on technician scope of practice.

Professional Judgment and Medication Use

The Council reviewed regulatory and accreditation standards requirements that limit the information that can be used to determine storage and stability of medications to approved product labeling (i.e., the package insert).

The Council agreed that, while product labeling is an important source of stability and storage information, it is the pharmacist's responsibility and within pharmacy scope of practice to use professional judgment to determine how drugs may appropriately be packaged, stored, administered, and recommended for particular clinical conditions.

Prohibiting use of stability data from non-FDA-approved sources, such as official compendia or other authoritative sources of drug information, has the potential to increase waste and worsen drug shortages. As the [ASHP Statement on the Pharmacist's Responsibility for Distribution and Control of Drug Products](#) is currently in revision, the Council forwarded a suggested revision recommending that organizational policies on storage and stability be supported by information in nationally recognized compendia or other authoritative references, or confirmation by the manufacturer that the use is appropriate, or scientific studies published in the biomedical literature.

ASHP Guidelines for Pharmacists on the Activities of Vendors' Representatives in Organized Healthcare Systems

Council members reviewed the draft ASHP Guidelines on the Pharmacist's Relationship with Industry, which will supersede these guidelines when finalized. Council members offered a number of additional revisions for consideration:

- Require tighter restrictions on vendor activity than those in the draft guidelines. Several Council members' institutions allow vendors to make appointments only with the Director of Pharmacy during a specified time routinely set aside for that purpose. Others meet with vendor representatives offsite due to accreditation standards requiring that vendors meet immunization and safety training requirements.
- Council members advised that practice managers should develop policies limiting the activities of physicians' assistants and nurse practitioners employed as representatives by certain companies. Some Council members have noted that these individuals divert hospital business to their specialty pharmacies while detailing their products and services.

Council members also suggested that sample vendor policies would be a useful practice manager resource.

Practice Implications for Remote Product Verification

The Council reviewed both [ASHP policy 0716, Regulation of Telepharmacy Services](#), and the current [ASHP Guidelines on Remote Medication Order Processing](#). The Council recommended that the Section of Pharmacy Informatics and Technology collaborate with the Council on Public Policy to consider revising these documents to include emerging technology for remote order verification and to ensure that adequate downtime procedures are developed. While the current guidance is comprehensive, innovation in this field has advanced rapidly and ASHP documents no longer reflect current practice.

The Council offered a number of proposed revisions:

- An amendment to ASHP policy 0716 that addresses remote product verification.
- Clarification of the phrases “remote double-checking of the completed medication order before dispensing” and “actual dispensing” in order to clearly convey that a final check required to verify that a product is dispensed as ordered.
- Consider the addition of more detailed recommendations in the guidelines for implementation of downtime procedures in remote facilities.
- Affirm that pharmacists must have access to all patient clinical information, rather than minimum elements.
- Consider reviewing and revising ASHP policy and guidance documents on hazardous medications to include implications for remote order and product verification. A significant proportion of oncology medications are prepared in clinics and community-based practices without oversight of a pharmacist.

Board Certification for Pharmacists

The Council reviewed the new business item and background as requested by the ASHP Section of Clinical Specialists and Scientists (SCSS) and submitted comments for readying the policy for the next step in the policy process. Council members provided a number of comments supporting the policy as well as potential obstacles or objections the policy might encounter in the approval process. The Council Secretary forwarded these comments to SCSS for their consideration.

Technician Licensure

As requested, the Council reviewed background and recommendations from the PPMI Summit in order to advise ASHP regarding its initiative to seek technician licensure rather than registration. Much of the Council’s discussion took place in conjunction with consideration of recommending a new policy for technician accountability.

In general, the Council believed the public would be well served by licensure of technicians, if licensure is clearly defined regarding scope of practice and application requirements. Council members provided examples illustrating that the differences among licensing, registration, and certification are not obvious or well understood. One state board,

Louisiana, already licenses technicians and requires PTCB certification and training in a Board-approved training program. Several Council members stated the requirements were the same in their states for registration.

Council members stated that licensure should require more than competency. It is a contract with the public that the licensed individual has a specialized skill and is responsible for using good judgment in performing his or her job, not simply a tracking and disciplinary procedure. The Council's recommendations were forwarded to the Council on Education and Workforce Development and the Council on Public Policy for incorporation into proposed policies on technician competency and licensing by state regulatory boards.

The Council agreed that licensure, subsequent to completion of an ASHP-accredited training program and PTCB certification, is required to develop the skilled technician workforce needed to support expanded roles for pharmacists. They recommended that all technicians become licensed but advised that one size might not fit all. Evolving technician roles might include independent decision-making responsibility for operational issues, informatics, and supervision.

Review of Documents in Development

The Council reviewed the document development plan for the next three-year period and forwarded recommendations continuation, discontinuation, or suspension to ASHP.

Appendix



ASHP Statement on the Pharmacist's Role in Medication Reconciliation

Position

1 The American Society of Health System Pharmacists (ASHP) believes that an effective
2 process for medication reconciliation reduces medication errors and supports safe
3 medication use by patients. ASHP encourages hospitals and health systems, including
4 community-based providers and managed care systems, to collaborate in organized,
5 multidisciplinary medication reconciliation programs to promote continuity of patient care.
6 ASHP further believes that pharmacists, because of their distinct knowledge, skills, and
7 abilities, are uniquely qualified to lead interdisciplinary efforts to establish and maintain an
8 effective medication reconciliation process in hospitals and across health systems.
9 Pharmacists should lead or assume key roles in the following essential components of
10 medication reconciliation: developing policies and procedures, implementing and
11 continuously improving medication reconciliation processes, training and assuring the
12 continuing competency of those involved in medication reconciliation, providing operational
13 and therapeutic expertise in the development of information systems that support
14 medication reconciliation, and advocating for medication reconciliation programs in the
15 community. Pursuant to their leadership role, pharmacists share accountability with other
16 hospital and health-system leaders for the ongoing success of medication reconciliation
17 processes across the continuum of care.

Background

18 The term “medication reconciliation” is defined by The Joint Commission (TJC) as “the
19 process of comparing the medications a patient is taking (and should be taking) with newly
20 ordered medications” in order to resolve discrepancies or potential problems.¹ The goals of
21 medication reconciliation are to obtain and maintain accurate and complete medication
22 information for a patient and use the information within and across the continuum of care
23 to ensure safe and effective medication use. Although it is sometimes associated with
24 survey and accreditation activities, medication reconciliation is an important component of
25 patient safety and has demonstrated effectiveness in preventing adverse drug events. When
26 organizations do not consistently and reliably reconcile patient medications across the
27 continuum of care, medication errors and adverse drug events occur: approximately half of
28 all hospital-related medication errors and 20% of all adverse drug events have been
29 attributed to poor communication at the transitions and interfaces of care.²⁻³

30 In 1999, the Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health*
31 *System*⁴ identified medication errors as the most common type of health-system error,
32 contributing to several thousand deaths each year. The fiscal impact of these errors is also
33 significant. With reported costs of \$2595–4685 per adverse drug event, drug-related
34 morbidity and mortality was estimated to be over \$177 billion in 2000 alone.⁵

35 Reports and studies such as these had a profound impact on the medical community,
36 and the call for action was immediate. Organizations such as the Institute for Healthcare
37 Improvement (IHI), the Agency for Healthcare Research and Quality (AHRQ), and TJC

38 launched initiatives for performance improvement and established higher expectations
39 through new regulatory standards for improved communication between providers and
40 patients and across health care systems.

41 In 2005, TJC made medication reconciliation a focus of one of its National Patient
42 Safety Goals. The initial goal included a number of detailed and specific requirements, which
43 made implementation challenging and resulted in numerous findings of noncompliance
44 during survey. In response, TJC affirmed the importance of the goal but suspended it in
45 2009 and 2010 for extensive revision. After a comprehensive literature review and analysis
46 of data collected by surveyor teams, a modified goal was released in 2011, and scoring of
47 the goal began in July 2011.⁶ The revised goal sets an expectation for maintaining accurate
48 medication information at critical risk points in the medication-use process while allowing
49 organizations latitude to define processes and encouraging performance improvement.

50 The purpose of this statement is to describe pharmacists' responsibilities and
51 accountabilities in medication reconciliation practices.

Pharmacists' Responsibilities

52 When performed by pharmacists, medication reconciliation can reduce the frequency and
53 severity of hospital medication errors that could potentially result in patient harm.⁷

54 Pharmacists have demonstrated high rates of patient interventions; interventions per
55 patient; and documentation of medications, medication interactions, drug-related
56 admissions, and previous drug failures.⁸

57 ASHP and the American Pharmacists Association (APhA) began a collaborative effort in
58 2007 and 2008 to create a shared vision for the role of the pharmacist in medication
59 reconciliation processes.⁹ That vision recognizes that pharmacists should take a leadership
60 role in improving medication reconciliation, acting as both advocates and medication
61 experts, to provide information to and educate patients and health care providers.
62 Specifically, pharmacists' responsibilities were described as including but not being limited
63 to

- 64 • providing leadership in designing and managing patient-centered medication
65 reconciliation systems,
- 66 • educating patients and health care professionals about the benefits and limitations
67 of the medication reconciliation process, and
- 68 • serving as patient advocates throughout transitions of care.

69 Using this vision as a guide, ASHP has developed the following recommendations for
70 pharmacists' functions in medication reconciliation activities.

Pharmacists' Functions

71 Although medication reconciliation is required at key transitions of care, activities
72 associated with medication reconciliation should be considered part of ongoing care
73 provided to a patient. Beyond active participation in medication reconciliation activities,
74 pharmacists have five fundamental functions in medication reconciliation: developing
75 policies and procedures regarding medication reconciliation processes, implementing and
76 continuously improving those processes, training and assuring the continuing competency
77 of those involved in medication reconciliation, providing operational and therapeutic
78 expertise in the development of information systems that support medication
79 reconciliation, and advocating for medication reconciliation programs in the community.

80 The extent of pharmacist involvement in these functions will depend on the resources
81 available.

82 **Policy and procedure development.** Pharmacists should provide leadership and
83 participate in establishing policies and procedures that encourage (a) provision of patient-
84 care services that include medication reconciliation processes, (b) implementation and
85 operation of an evidence-based medication reconciliation system that optimizes available
86 resources, (c) education of organization staff on the importance of medication reconciliation
87 as a patient safety initiative, and (d) promotion of medication reconciliation as a focus of
88 performance improvement activities.

89 **Implementation and performance improvement.** Pharmacists should lead or
90 participate in organizational implementation of and performance improvement efforts
91 regarding medication reconciliation activities. These activities may include but are not
92 limited to: (a) establishing a medication reconciliation implementation task force or
93 redesign team; (b) creating a vision and expectations for medication reconciliation activities;
94 (c) securing executive-level commitment to or sponsorship of medication reconciliation
95 resource needs; (d) identifying barriers that are preventing, or potential barriers that may
96 prevent, safe and effective medication reconciliation procedures within their practice
97 model, as well as possible solutions; (e) guiding workflow development that integrates
98 operational and clinical needs; (f) establishing roles and responsibilities of health care
99 providers in medication reconciliation processes, including pharmacy technicians, pharmacy
100 students, and other medical support personnel; (g) ensuring that competency-based
101 training for all personnel involved in medication reconciliation procedures is established; (h)
102 creating or assisting in the development of standardized documentation templates for
103 medication lists and reconciliation; (i) ensuring that established procedures meet regulatory
104 requirements and organizational policy; and (j) developing a method for ongoing medication
105 reconciliation system evaluation.

106 **Training and competency assurance.** Pharmacists should lead or participate in (a)
107 identifying all health care providers and support staff involved in medication reconciliation
108 activities; (b) creating competency training and skills assessment that are specific to each
109 staff member's roles and responsibilities in medication reconciliation (e.g., conducting a
110 medication interview, taking a medication history, performing medication reconciliation);
111 (c) providing education and performing assessments to ensure the competency of those
112 who document and perform medication reconciliation activities; and (d) providing didactic
113 or simulated training for medication history and reconciliation procedures.

114 **Information systems development.** As more organizations adopt computerized
115 provider order entry, electronic medical records, and other information systems,
116 pharmacists should ensure that the systems support medication reconciliation throughout
117 the continuum of care. Consideration should be given to establishing methods for data
118 extraction from the medical record that allow for internal and external reporting of
119 measures related to medication reconciliation.

120 **Advocacy.** Pharmacists should provide information about medication reconciliation to
121 health care providers, patients, and the community, and they should evaluate the
122 effectiveness of these advocacy efforts on the medication reconciliation process. Activities
123 may include clinical grand rounds, professional conferences, patient counseling, or mass
124 communications such as newsletters or public service announcements. These efforts should
125 (a) demonstrate the effectiveness of sound medication reconciliation processes in

126 improving patient safety and reducing health care costs; (b) emphasize the importance of
127 timely and accurate communication of medication information between patients and their
128 health care providers; (c) clarify and describe the important role of technology and
129 electronic medical records that support medication reconciliation documentation and
130 reconciliation; (d) provide strategies for preventing medication adverse events related to
131 overuse, misuse, omission, duplication, or other discrepancies found during medication
132 reconciliation processes; (e) highlight the importance of completing a full and accurate
133 medication history, including supplement use, prior to prescribing or administering a new
134 medication; and (f) describe opportunities for pharmacist extenders, such as pharmacy
135 technicians and students, to participate in medication reconciliation activities.

136 **Resource constraints.** Although the literature demonstrates the important role of
137 pharmacists in successful medication reconciliation processes across the continuum of care,
138 significant resources are needed to perform medication reconciliation skillfully and
139 efficiently, which suggests opportunities for expanding the roles of pharmacy residents,
140 students, and technicians. When properly trained, these individuals can participate in the
141 documentation of medication histories, which should then be reviewed by the pharmacist
142 for accuracy prior to medication reconciliation, as described in the ASHP Pharmacy Practice
143 Model Initiative Summit Recommendations.¹⁰ In one study, potential errors due to
144 incomplete or incorrect information, illegible orders, and serious drug interactions were
145 reduced by 82% by having pharmacy technicians obtain medication histories.¹¹

146 When confronted with limited resources, pharmacists should at a minimum participate
147 in and guide interdisciplinary efforts to develop and define policies and procedures for their
148 organizations, standardize workflows for electronic documentation, promote safe practices
149 to the community, and, most importantly, engage health care leadership in efforts to ensure
150 medication reconciliation processes are successful.

Conclusion

151 An effective process for medication reconciliation reduces medication errors and supports
152 safe medication use. Pharmacists are uniquely qualified to lead interdisciplinary efforts to
153 establish and maintain an effective medication reconciliation process in hospitals and across
154 health systems and should lead or assume key roles in the essential components of
155 medication reconciliation. Because of their crucial role, pharmacists share accountability
156 with other hospital and health-system leaders for the ongoing success of medication
157 reconciliation processes across the continuum of care.

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SEIZE THE INITIATIVE

ASHP House of Delegates 2012
June 10 and 12, 2012

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.

Christene M. Jolowsky, *Board Liaison*

Council Members

- Amber J. Lucas, *Chair* (Kansas)
- Melanie A. Dodd, *Vice Chair* (New Mexico)
- Emily Alexander (Texas)
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- Michele Hodges Simmons, *Student* (North Carolina)
- Greg A. Teale (Missouri)
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- Brian M. Meyer, *Secretary*

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Policy Recommendations



A. Licensure of Pharmacy Technicians

1 To advocate that pharmacy move toward the following model with respect to
2 technicians as the optimal approach to protecting public health and safety: (1)
3 development and adoption of uniform state laws and regulations regarding licensure
4 of pharmacy technicians, (2) mandatory completion of an ASHP-accredited program
5 of education and training as a prerequisite to pharmacy technician certification, (3)
6 mandatory certification by the Pharmacy Technician Certification Board as a
7 prerequisite to licensure by the state board of pharmacy, and (4) licensure of
8 pharmacy technicians by state boards of pharmacy granting the technician permission
9 to engage in the full scope of responsibilities authorized by the state; further,

10 To advocate licensure of pharmacy technicians by state boards of pharmacy; further,

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

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

19 (Note: Licensure is the process by which an agency of government grants permission
20 to an individual to engage in a given occupation upon finding that the applicant has
21 attained the minimal degree of competency necessary to ensure that the public
22 health, safety, and welfare will be reasonably well protected. Certification is the
23 process by which a nongovernmental agency or association grants recognition to an
24 individual who has met certain predetermined qualifications specified by that agency
25 or association.)

(Note: This policy would supersede ASHP policy 0815.)

Rationale

ASHP policy 0815 was revised to advocate for licensure of pharmacy technicians in response to Recommendation D8 by the [Pharmacy Practice Model Initiative](#) (PPMI) Summit and subsequent discussion by the ASHP Board of Directors. Optimal use of pharmacy technicians will enable pharmacists to devote more time to drug therapy management. Uniformity among state laws is

essential to achieve the preferred vision for practice. Moreover, requiring licensure rather than registration will enable state boards to require competency, impose disciplinary sanctions, and hold technicians accountable for their actions.

The process proposed for pharmacy technicians to achieve licensure follows the same steps outlined in policy 0815: education and training, followed by examination and certification, as prerequisites to licensure. The movement to technician licensure was essential to assure the public that the medication-use system includes individuals competent to assist pharmacists to provide and manage their medication regimens. Licensure will provide state boards with the tools necessary to provide that assurance to the public.

Background

The Council recommended and the Board voted to revise ASHP policy 0815, Uniform State Laws and Regulations Regarding Pharmacy Technicians, as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To advocate that pharmacy move toward the following model with respect to technicians as the optimal approach to protecting public health and safety: (1) development and adoption of uniform state laws and regulations regarding licensure of pharmacy technicians, (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy technician certification, ~~and~~ (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to licensure by the state board of pharmacy, and (4) licensure of pharmacy technicians by state boards of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

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

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

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

(Note: Licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. ~~Registration is the process of making a list or being enrolled in an existing list;~~

~~registration should be used to help safeguard the public through interstate and intrastate tracking of the technician work force and preventing individuals with documented problems from serving as pharmacy technicians.)~~

This policy recommendation resulted from Recommendation D8 of the PPMI Summit, which calls for licensure by state boards of pharmacy that would support optimal models and the desired future state of pharmacy practice in hospitals and health systems. The Council and Board recognized that this policy and the advocacy required to achieve these changes in all 50 states would require a long-term effort. However, it was agreed that it is essential to begin the process by revising the policy to prepare the pharmacy workforce to meet the current challenges of our preferred practice vision.



B. Opposition to Creation of New Categories of Licensed Personnel

- 1 To discontinue ASHP policy 0521, which reads:
- 2 To reaffirm the following statement in the White Paper on Pharmacy Technicians
- 3 (April 1996) endorsed by ASHP and the American Pharmacists Association:
- 4 "Although there is a compelling need for pharmacists to expand the
- 5 purview of their professional practice, there is also a need for pharmacists
- 6 to maintain control over all aspects of drug product handling in the patient
- 7 care arena, including dispensing and compounding. No other discipline is as
- 8 well qualified to ensure public safety in this important aspect of health
- 9 care."
- 10 Further,
- 11 To oppose the creation of new categories of licensed pharmacy personnel;
- 12 further,
- 13 To advocate that all professional pharmacy functions be performed under the
- 14 supervision of a licensed pharmacist to avoid confusion regarding the roles of
- 15 pharmacy personnel within health systems.

Background

In light of the revision to policy 0815 (discussed above), the Council recommended and the Board voted to discontinue policy 0521. Policy 0521 and related language in the White Paper on Pharmacy Technicians were intended to prevent reemergence of licensed categories in state practice acts such as pharmacist assistant or assistant pharmacist. Those efforts have been dormant, and the Council and Board feel the policy is no longer relevant. Moreover, the Council's previous discussion in revising policy 0815 emphasized the need to respond to the

recommendations of the PPMI and subsequent discussion by the Board of Directors. The Council and Board observed that if policy 0521 is not discontinued, advocacy of pharmacy technician licensure could not be supported.



C. Pharmacy Technicians

- 1 To discontinue ASHP policy 8610, which reads:
 - 2 To work toward the removal of legislative and regulatory barriers preventing
 - 3 pharmacists from delegating certain technical activities to other trained
 - 4 personnel.

Background

In light of revisions to policy 0815 (discussed above), the Council recommended and the Board voted to discontinue policy 8610. Policy 8610 was adopted by the House of Delegates over 25 years ago and was intended to allow pharmacists the ability to safely and efficiently utilize the skills of technicians and other personnel. State practice acts and technician regulation have evolved considerably since then. Moreover, the Council and Board believe the policy recommendation above concerning licensure of technicians would more comprehensively describe ASHP's current policy and include the intent of policy 8610.



D. Collaborative Drug Therapy Management

- 1 To pursue the development of federal and state legislative and regulatory provisions
- 2 that authorize collaborative drug therapy management by pharmacists; further,
 - 3 To advocate expansion of federal and state legislative and regulatory provisions that
 - 4 optimize pharmacists' ability to provide the full range of professional services within
 - 5 their scope of expertise; further,
 - 6 To acknowledge that as part of these advanced collaborative practices, pharmacists,
 - 7 as active members in team-based care, must be responsible and accountable for
 - 8 medication-related outcomes; further,
 - 9 To support affiliated state societies in the pursuit of state-level collaborative drug
 - 10 therapy management authority for pharmacists.

(Note: This policy would supersede ASHP policy 9812.)

Rationale

ASHP policy 9812 was revised to (1) explicitly include in the second clause the need to expand a pharmacist's scope of practice to allow them to practice to the fullest extent of their expertise, and (2) acknowledge in the third clause that pharmacists are part of the interdisciplinary team and are accountable to the patient and the team for all medication-related outcomes. With these changes, the policy expresses the concept of pharmacists' professional identity and autonomy while providing their unique expertise and practice as part of an interdependent and interdisciplinary health care team focused on achieving the best patient outcomes.

Although more than 43 states permit collaborative drug therapy management (CDTM), there is great variability in the authority granted to pharmacists engaged in CDTM. With this policy, ASHP reiterates its support for CDTM and advocates for its expansion to all states, in a variety of diverse practice settings, and at the highest level of pharmacy practice. As new practice models emerge as recommended by the PPMI, CDTM should be a part of those innovations. The addition of these clauses in policy 9812 will aid in moving the profession forward to the highest level of practice and enable pharmacists to practice at the top of their licenses.

Background

The Council recommended and the Board with amendment voted to revise ASHP policy 9812, Collaborative Drug Therapy Management, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To pursue the development of federal and state legislative and regulatory provisions that authorize collaborative drug therapy management by ~~the pharmacists as a component of medication therapy management pharmaceutical care~~; further,

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

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

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

The Council's discussion of this issue and decision to revise policy 9812 was in response to the growing interest among all health professions to practice to the fullest extent of their scope of practice in order to provide the best possible care to patients as part of an interdisciplinary team. In addition, a recommendation by the PPMI Summit stated, "[t]hrough credentialing and privileging processes, pharmacists should include in their scope of practice prescribing as part of the collaborative practice team." These two factors prompted a review by the Council and its decision to strengthen the policy by adding the two additional clauses. The Council also noted the relationship to [ASHP policies 9801](#), which defines CDTM, and [0905](#), which discusses the importance of credentialing and privileging for providing CDTM, as well as compensation for these services. Council members also observed the need to engage payers in discussing effective payment models in alignment with accountability for medication-related outcomes.



E. Approval of Biosimilar Medications

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

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

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

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

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

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

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

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

(Note: This policy would supersede ASHP policy 0906.)

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. The FDA is developing its implementing regulations in order to consider applications from manufacturers. Policy 0906 was revised to reflect use of the terms “biosimilar” and “interchangeable” in the Affordable Care Act and its subtitles. In addition, a clause was added to advocate that FDA determine interchangeability with a reference product, thereby allowing for the substitution of a biosimilar product through a hospital or health system’s formulary process and pharmacy and therapeutics committee (or similar entity). In light of these developments, there is a need for ASHP-developed education about biosimilars, with a particular emphasis on the role of formulary systems in determining the appropriate use of these medications.

Background

The Council recommended and the Board voted to revise ASHP policy 0906, Approval of Follow-on Biological Medications, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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

To encourage research on the safety, effectiveness, and interchangeability of biosimilar ~~follow-on biological~~ medications; further,

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

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

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

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

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

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar ~~follow-on biological~~ medications are used in 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.)~~



F. Stable Funding for HRSA Office of Pharmacy Affairs

- 1 To advocate for a sustainable level of funding, including appropriations, sufficient to
- 2 support the public health mission of the Health Resources and Services
- 3 Administration (HRSA) Office of Pharmacy Affairs; further,
- 4 To support initiatives of the Office of Pharmacy Affairs, including the 340B Drug
- 5 Pricing Program and innovative pharmacy service models in HRSA-funded programs;
- 6 further,
- 7 To encourage research on the potential impact of any proposed fees or alternative
- 8 funding sources for the Office of Pharmacy Affairs.

(Note: This policy would supersede ASHP policy 0911.)

Rationale

The Office of Pharmacy Affairs (OPA) currently relies on general funding from its parent agency, HRSA, and not a line-item annual appropriation to administer the 340B Drug Discount Program. The OPA and HRSA have sought funding to establish a cost recovery (user fee) program to administer the program. The initial fee would be 0.1 percent of the total 340B drug purchases paid by participating covered entities. HRSA and OPA contend that the cost recovery fee will create a sustainable funding source to meet the demands of the existing and projected growth of the 340B program, the changing marketplace, and new statutory program requirements. There is a need for stable and sustainable funding for the OPA. A variety of funding sources should be considered, perhaps involving entities that do not participate in the 340B program. Any user fee program should include an annual review of the percentage used to determine the annual fee charged to participating entities. In addition, OPA should not be solely dependent on user fees for its program administration; some level of congressional appropriations would serve as an important safeguard against such a dependency.

Background

The Council recommended and the Board voted to revise ASHP policy 0911, Stable Funding for Office of Pharmacy Affairs, as follows (underscore indicates new text; ~~strike through~~ indicates deletions):

To advocate for a sustainable level of adequate funding, including appropriations, sufficient to support the public health mission of ~~for~~ the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs ~~to support its public health mission;~~ further,

To support initiatives of the Office of Pharmacy Affairs, including the 340B Drug Pricing Program and innovative pharmacy service models in HRSA-funded programs; further,

To encourage research on the potential impact of any proposed fees or alternative funding sources for the Office of Pharmacy Affairs.



G. Standardized Immunization Authority to Improve Public Health

- 1 To advocate that, to improve public health and patient access to immunizations,
- 2 states grant pharmacists the authority to initiate and administer all adult and child
- 3 immunizations through a universal protocol developed by state health authorities;
- 4 further,

- 5 To advocate that only pharmacists who have completed a training and certification
- 6 program acceptable to state boards of pharmacy and meeting the standards established
- 7 by the Centers for Disease Control and Prevention may provide such immunizations;
- 8 further,

- 9 To advocate that state health authorities establish a centralized database for
- 10 documenting administration of immunizations that is accessible to all health care
- 11 providers.

Rationale

Increasing adult and pediatric patients' access to immunizations is an important public health challenge. Pharmacists' unique training and expertise in all aspects of the medication-use system can help expand patients' access to immunizations and promote disease prevention. Hospital and health-system pharmacists provide care to a patient population that is vulnerable and often critically ill, and such patients are especially dependent on herd immunity. Patients in rural areas, where a pharmacy may provide the only convenient access to a health care professional, will benefit from increased pharmacist immunization authority.

Although all states permit pharmacist administration of some vaccines, state laws differ in the range of vaccines pharmacists may administer and the patient populations they are permitted to vaccinate. A universal administration protocol developed by state health departments would, in contrast, encourage standardization of pharmacy immunization practice within and among states. In addition, under such a protocol, it would not be necessary for pharmacist-provided immunizations to be conducted within a collaborative drug therapy management agreement.

Only pharmacists who undergo appropriate training and certification should be authorized by state boards to provide immunizations. To ensure their consistency and quality, those training and certification programs should meet Centers for Disease Control and Prevention (CDC) standards. Finally, to aid in sharing important patient immunization information, a central database of patient immunizations should be established with access by primary care providers and other authorized practitioners.

Background

The Council recommended and the Board with amendment voted to approve this new policy in response to a delegate recommendation seeking ASHP advocacy for standardization of pharmacist authority to administer vaccinations.



H. Automated Systems

- 1 To discontinue ASHP policy 9205, which reads:
- 2 To support the use of current and emerging technology in the advancement
- 3 of pharmaceutical care; further,
- 4 To encourage a review and evaluation of the state and federal legal and
- 5 regulatory status of new technologies as they apply to pharmacy practice.

Background

As part of its sunset review, the Council reviewed policy 9205. The Council and Board concluded that other ASHP policies addressed the intent of the policy. The Council and Board also noted

that since the policy was adopted in 1992, ASHP has established the Section of Pharmacy Informatics and Technology, which has developed substantial guidance for members on this topic. The Council recommended and the Board voted to discontinue the policy.



I. Medical Devices

- 1 To discontinue ASHP policy 9106, which reads:
- 2 To support public and private initiatives to clarify and define the relationship
- 3 among drugs, devices, and new technologies in order to promote safety and
- 4 effectiveness as well as better delivery of patient care.

Background

As part of its sunset review, the Council reviewed policy 9106. The Council and the Board agreed that other ASHP policies better address the intent of the policy, which was developed as Congress was developing legislation to better define a medical device and provide for problem-reporting to the FDA. The Council recommended and the Board voted to discontinue the policy.

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.)

- [Restricted Drug Distribution](#) (0714)
- [Patient Access to Orphan Drug Products](#) (0715)
- [Regulation of Telepharmacy Services](#) (0716)
- [FDA Authority to Prohibit Reuse of Brand Names](#) (0719)
- [Standardizing Prefixes and Suffixes in Drug Product Names](#) (0720)
- [Pharmacist Recruitment and Retention](#) (0218)
- [Intermediate Category of Drugs](#) (0220)
- [Greater Access to Less Expensive Generic Drugs](#) (0222)
- [Drug Samples](#) (9702)
- [Manufacturer-Sponsored Patient Assistance Programs](#) (9703)
- [Drug Testing](#) (9103)
- [Employee Testing](#) (9108)
- [Codes on Solid Dosage Forms of Prescription Drug Products](#) (8709)
- [Size, Color, and Shape of Drug Products](#) (8310)

Other Council Activity

Statement on Pharmacy Technician Workforce

In the Council's discussion that led to revision of ASHP policy 0815 and discontinuation of policies 0521 and 8610, it became clear that an ASHP statement that describes the desired scope of practice for a licensed pharmacy technician was necessary. The Council believed that merely inserting "licensure" for "registration" in existing policy was only one component of the policy actions needed to move toward licensure. In addition, the Council's discussion emanated from the recommendations of the PPMI and discussion by the Board of Directors.

Thus, the Council voted to draft an ASHP statement on the pharmacy technician workforce that addresses technician scope of practice and describes whether there are (1) functions for which a licensed pharmacy technician is fully responsible and accountable, and (2) functions for which there is shared responsibility and accountability between the licensed pharmacy technician and the pharmacists.

The Council felt that a statement that describes a licensed pharmacy technician's scope of practice could further explain the duties and functions as well as delineate those that would involve shared responsibility and accountability. Additional areas contained in a statement would include the need for education and training, examination and certification, disciplinary sanctions, and the functions authorized to be performed independently, without the supervision of a pharmacist, and those requiring pharmacist supervision.

The Council noted that the statement could also address the ability of health systems to require specific credentials in order for pharmacy technicians to practice in their organization. Council members also suggested that expansion and inclusion of more community-based questions in the Pharmacy Technician Certification Board examination would position it as a generalist exam. The Council also noted that the specific recommendations from the PPMI Summit as well as from states that currently license pharmacy technicians would aid in developing the statement.

Board Certification of Pharmacists

The Council discussed the new business item proposed by the Section of Clinical Specialists and Scientists concerning certification and the role of the Board of Pharmacy Specialties. The Council understood the rationale for the proposal by the Section and offered some commentary. Specifically, it suggested addressing certification where a subspecialty may be formally recognized by the profession. The Council agreed that credential and exam requirements need to be streamlined, with uniform eligibility criteria between the various subspecialty (i.e., non-Pharmacotherapy) exams. Finally, Council members suggested that the policy include a statement that any future eligibility include residency training.

Prescription Drug User Fee Act Reauthorization

The Council reviewed the process and timeline for reauthorization of the Prescription Drug User Fee Act (PDUFA), which is contained in the Food, Drug and Cosmetic (FD&C) Act. PDUFA expires every five years, and it must be renewed by Congress by September 30, 2012. It allows for the

collection of user fees from manufacturers in exchange for the FDA meeting certain performance goals as part of the drug approval process. The Council reviewed current ASHP policies and noted the opportunity to make changes to the FD&C Act during the reauthorization process. The Council noted existing ASHP policy as part of ASHP's advocacy as the FDA finalizes its recommendations to Congress and during the legislative process. Specifically identified were policies relating to product recalls, transparency of information about clinical trial design, and FDA's evaluation using evidence-based medicine. Also identified were risk/benefit communication and the use of risk evaluation and mitigation strategies (REMS), particularly those REMS requiring additional elements to assure safe use. Additional issues discussed included FDA governance, direct-to-consumer/purchaser/prescriber communications, and information technology issues associated with National Drug Code numbering.

Standardized Pharmacist Licensure Reciprocity

In response to a delegate recommendation, the Council discussed the notion of streamlining licensure reciprocity to allow for a pharmacist to reciprocate either their original state license or from their current state license (if not the original state). The Council noted the benefit and intent of the recommendation as part of discussions with the National Association of State Boards of Pharmacy (NABP). The Council also reviewed [ASHP policy 0612, Streamlined Licensure Reciprocity](#), and felt it was useful and broad enough to aid in any discussions with NABP.

ASHP Statement on Confidentiality of Patient Health Care Information

In response to a delegate recommendation, the Council discussed the [ASHP Statement on Confidentiality of Patient Health Care Information](#). The Council noted that provisions in the Health Information Technology for Economic and Clinical Health (HITECH) Act and subsequent regulations may suggest a need for changes to the ASHP statement. However, the Council felt that over the course of the following year, the regulatory picture may become clearer. At that point, the Council will revisit the recommendation to update the statement.



SEIZE THE INITIATIVE

**ASHP House of Delegates 2012
June 10 and 12, 2012**

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.

Michael D. Sanborn, *Board Liaison*

Council Members

Jill S. Bates, *Chair* (North Carolina)
 Catherine D. Johnson, *Vice Chair* (Wisconsin)
 Linda W. Banares, *New Practitioner* (California)
 Curtis D. Collins (Michigan)
 Edward H. Eiland III (Alabama)
 Elizabeth K. Gorski, *Student* (Illinois)
 Joel A. Hennenfent (Missouri)
 Joel C. Marrs (Colorado)
 Margaret E. McGuinness (Oregon)
 Rachel A. Ranz (Indiana)
 Kenneth M. Shermock, Jr. (Maryland)
 Kersten Weber Tatarelis (Illinois)
 Erin R. Fox, *Section of Clinical Specialists and Scientists Liaison* (Utah)
 Cynthia Reilly, *Secretary*

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Policy Recommendations



A. Criteria for Medication Use in Geriatric Patients

- 1 To support medication therapy management, including assessment of physiologic and
2 pharmacokinetic factors, as a central component of providing safe and effective drug
3 therapy to geriatric patients; further,

- 4 To oppose use of the Beers criteria by the Centers for Medicare & Medicaid Services
5 and other accreditation and quality improvement entities as an indicator to assess the
6 appropriateness of prescribing for geriatric patients based on known limitations in the
7 development of that tool and evidence suggesting a lack of association between use
8 of medications listed in the Beers criteria and subsequent adverse drug events;
9 further,

- 10 To advocate for the development, refinement, and validation of new criteria that
11 consider drug-, disease-, and patient-specific factors and demonstrate the ability to
12 decrease the occurrence of adverse drug events in geriatric patients; further,

- 13 To support research to assess the clinical application of existing and proposed criteria,
14 including assessment of their correlation to patient outcomes and strategies for
15 implementation; further,

- 16 To encourage inclusion of validated criteria in clinical decision support systems and
17 other information technologies to facilitate prescribing for geriatric patients; further,

- 18 To acknowledge that such criteria are intended as a guide and should not replace the
19 clinical judgment of pharmacists and other clinicians.

Rationale

Criteria have been developed to identify high-risk drugs that should be avoided in geriatric patients (i.e., those 65 years of age or older) based on the potential for these therapies to cause adverse drug events that can result in falls, hospitalizations, and other incidents that lead to significant morbidity and mortality in this patient population. Those criteria include the 2002 iteration of the [Beers criteria](#) (published in 2003) and the [Screening Tool of Older Persons' Potentially Inappropriate Prescriptions](#), or STOPP. Although ASHP supports the intent of these criteria to prevent patient harm, safe and effective use of medications in geriatric patients requires the more thorough assessment associated with pharmacist-provided medication therapy management. ASHP opposes adoption of the Beers criteria by the Centers for Medicare & Medicaid Services (CMS) other accreditation and quality improvement organizations as a tool

to assess prescribing in the long-term care and other settings, noting concerns about the development and validation of that tool. More importantly, studies evaluating the clinical application of Beers criteria have not demonstrated a reduction in adverse events when that tool is used. In that regard, STOPP, which is based on organ systems and accounts for patients' concomitant disease, is considered more useful. Studies evaluating STOPP, though small in number, project a favorable impact on patient outcomes. ASHP encourages additional work to develop, refine, and validate this and similar evidence-based criteria. Further, there is a need for practice-based research to evaluate the application of such criteria and inclusion of validated criteria in clinical decision support systems and other information technologies is necessary to facilitate the use of these criteria in clinical practice. Finally, these tools are intended to serve as a guide or screening tool and should not replace the clinical judgment of pharmacists and other clinicians.

Background

The Council revisited the use of prescribing criteria intended to ensure safe drug therapy in geriatric patients by avoiding therapies that may be associated with an increased risk of adverse drug events in that patient population. This topic was first addressed by the Council in 2007 when the 2002 iteration of the Beers criteria and Assessing Care of Vulnerable Elders (ACOVE) criteria were reviewed. At that time, the Council stated that there was no ideal system for measuring appropriate prescribing in geriatric patients and noted that additional research was needed to validate the ability of these criteria to improve patient outcomes. This year, the Council compared those previously reviewed criteria to STOPP, a new tool that was evaluated in a study published in the *Archives of Internal Medicine* in June 2011. In that and other evaluations, researchers concluded that use of STOPP would prevent adverse drug events in geriatric patients. Other available criteria or tools include a drug burden index, which assesses the impact of drug therapy on physical and cognitive function based on pharmacologic principles, and the medication appropriateness index, which assesses the overall quality of prescribing. While supporting the intent of prescribing criteria, the Council and Board strongly advocated for pharmacist-provided medication therapy management (MTM) as a primary mechanism to ensure safe drug therapy in this patient population. MTM, which utilizes the drug therapy expertise of a pharmacist, was considered superior to explicit criteria, such as the Beers criteria, that are easy to implement but limited by their checklist or "black and white" nature. It was noted that pharmacist review should include an assessment of pharmacokinetic and pharmacodynamic factors, as well other drug-, disease-, and patient-specific factors. The Council strongly believed that prescribing criteria should be used to augment or facilitate, not replace, the pharmacist's clinical judgment. The Board agreed.

The Council noted that CMS included the Beers criteria in its interpretive guidelines for evaluating medication use in the long-term-care setting. The Council and Board opposed this use by CMS and other organizations based on concerns about the processes used to develop and validate the Beers criteria, as well as a lack of evidence demonstrating its ability to prevent adverse drug events when applied in the clinical setting. The Council described the Beers criteria as a checklist of drugs that largely fails to address other factors, including patient-specific factors, that affect the safety of drug therapy, and the Board concurred. Several drugs on the list, including propoxyphene, are no longer available. In addition, it was suggested that

other therapies defined by Beers criteria should not be on the list because use of those therapies may be appropriate in some geriatric patients. Council members also noted that the current iteration of the Beers criteria fails to address many therapies used in the inpatient setting. [Note: The American Geriatric Society is currently updating the 2002 iteration of the Beers criteria, which were published in the *Archives of Internal Medicine* in December 2003. It is anticipated that the update will address some concerns (e.g., removal of drugs no longer available) but not all of the shortcomings (e.g., lack of validation) described by the Council.]

The Council and Board were encouraged by early evaluations of the STOPP criteria that demonstrated a favorable effect on patient outcomes, including the potential to prevent adverse drug event (ADE)-related hospitalizations. It was noted that STOPP incorporated a stronger focus on organ function and other factors that can affect the safe use of drugs in geriatric patients. Additional advantages of STOPP are that it has been evaluated prospectively in the inpatient setting in a study comparing its use to usual care. The Council acknowledged that the extent of data from current trials evaluating STOPP was limited and encouraged additional studies to validate the tool. The Board agreed with this assessment and recommendation. In addition, the need to adapt STOPP to reflect medications available in the United States was noted.

The Council also discussed the practical application of prescribing criteria, including their ease of use. It was noted that the Beers criteria is easy to implement, which may lead to increased use, despite its limitations. High workload and lack of access to information via clinical decision support systems and other information technologies were noted as barriers to using existing or future criteria. In addition to outcomes research, the Council and Board encouraged research to determine best strategies for implementing prescribing criteria to guide drug selection for geriatric patients. The Council believed that such research could demonstrate a positive return on investment to support salaries for the increased staff needed to complete this assessment when compared to the costs of adverse drug events that would be averted. Further, the Council encouraged inclusion of validated criteria within information technology systems to facilitate their use. The need for increased pharmacist knowledge about the complexity of drug therapy in the geriatric patients was also noted.



B. Medication Adherence

- 1 To recognize that improving medication adherence should be a key component of
2 strategies to improve the quality and safety of patient care only when adherence
3 improvement efforts include the following as required elements: (1) assessing the
4 appropriateness of therapy, (2) providing patient education, and (3) ensuring patient
5 comprehension of information necessary to support safe and appropriate use of
6 prescribed therapies; further,
- 7 To advocate that pharmacists, because of their distinct knowledge, skills, and abilities,
8 should take a leadership role in multidisciplinary efforts to develop, implement,
9 monitor, and maintain effective strategies for improving medication adherence;
10 further,
- 11 To recognize that clinicians, patients, and caregivers share accountability for the
12 outcomes of medication therapies, and that the central role patients and their
13 caregivers have in disease management includes responsibility for following
14 instructions for safe and effective medication use; further,
- 15 To encourage development, evaluation, and dissemination of models that improve
16 adherence, including those that combine existing strategies that have demonstrated
17 effectiveness; further,
- 18 To support the development of mechanisms to document medication adherence
19 interventions, including information technology solutions; further,
- 20 To advocate for payment models that facilitate an expanded role for pharmacists in
21 medication adherence efforts.

Rationale

The need to improve medication adherence as a cornerstone of efforts to improve patient care outcomes is widely recognized. A [2010 New England Journal of Medicine editorial](#) issued a call to action to improve adherence based on estimates that 50 percent of all patients are non-adherent, resulting in an estimated \$100 billion spent annually on avoidable hospitalizations. ASHP supports programs to improve adherence, but such efforts are not useful, and are perhaps harmful, if they fail to (1) assess the appropriateness of therapy, (2) provide patient education, and (3) ensure patient comprehension of information necessary to support safe and appropriate use of prescribed therapies. Pharmacists are the ideal clinician to lead multidisciplinary efforts to improve medication adherence based on their distinct knowledge, skills, and abilities related to drug therapy management. Other members of the

multidisciplinary team could include physicians, nurses, health psychologists, and social workers. Patients and their caregivers must share accountability with clinicians for medication outcomes, including the responsibility for following instructions for safe and effective medication use. Otherwise, the results from efforts of pharmacists and other clinicians would be negligible. Some interventions to improve medication adherence have shown favorable results, but the greatest success is achieved by models that incorporate multiple strategies reinforced over time. Therefore, the development, evaluation, and dissemination of models that use multimodal approaches are encouraged. The development of information technology solutions and other mechanisms to document interventions intended to improve medication adherence are also recommended. Further, payment models that support an expanded role for pharmacists in medication adherence efforts should be pursued.

Background

The Council discussed the increased prominence of medication adherence in efforts to improve the quality and safety of health care. A recent *New England Journal of Medicine* editorial issued a call to action to improve adherence as a cornerstone of health care reform, noting that 50 percent of all patients are non-adherent, resulting in an estimated \$100 billion spent annually on avoidable hospitalizations. Quality improvement organizations, including the National Quality Forum, have provided quality measures for medication management that focus on measuring medication adherence. The Council appreciated the intent of these efforts, but believed that traditional efforts to improve medication adherence focus too heavily on whether the patient is taking a medication and fail to assess the appropriateness of prescribed therapies, provide patient education on the appropriate use of prescribed therapies, and ensure patient comprehension of that information. The Council believed these elements were essential to adherence improvement efforts and the Board concurred with this assessment. The Council also discussed best practices and the role of pharmacists in this work. Pharmacists were considered the ideal clinician to lead medication adherence efforts based on their drug therapy expertise. However, the Council and Board strongly encouraged a multidisciplinary approach that maximizes the unique skills of all team members, which could include physicians, nurses, health psychologists, and social workers. For example, it was noted that pharmacists have limited training in behavioral interventions—an area where the expertise of health psychologists would be beneficial. Pharmacy residents and students were also identified as key team members that could augment existing staff resources. The Council strongly believed that patients and their caregivers must share accountability with clinicians for medication outcomes, including the responsibility for following instructions for safe and effective medication use, and the Board agreed. It was suggested that pharmacy benefit managers and other insurers should also share responsibility in improving adherence. It was noted that there are sometimes dueling priorities between the cost containment aspect of formulary management and the ability to simplify drug regimens, which has been shown to improve adherence. For example, formulary restrictions in the inpatient setting may require that hospitalized patients be switched from once daily formulations to formulations that require multiple doses per day.

The Council and Board noted that efforts to improve adherence are especially important at transitions of care, where improvements can minimize the risk of rehospitalizations and other adverse drug events. Successful interventions include simplifying medication regimens, as

well as more innovative models that incorporate reminder calls and visits or medication event monitoring systems (i.e., electronic caps that monitor patient access to prescription vials). The Council stated that no strategy is perfect and that those with increased effectiveness are often associated with increased cost or burden to implement. Approaches that incorporate a number of strategies implemented on an ongoing or repeated basis frequently achieved better results. Therefore, the Council and Board encouraged development, evaluation, and dissemination of models that combine the most effective strategies.

The Council also considered existing approaches to measuring medication adherence, including medication possession ratios, patient report questionnaires, and medication event monitoring systems. The Council noted that most approaches had value, but believed that variability in the selection of measures inhibits the ability to evaluate and compare interventions. The Council did not recommend additional research to determine the ideal measure, but rather encouraged selection and more consistent use of a measure from among those that already exist. The Council recommended educational programming or an article in the *American Journal of Health-System Pharmacy (AJHP)* that would provide an overview of existing measures and the pros and cons of their use. The Board supported the need for education on this topic. Development and dissemination of best practices to improve medication adherence was also encouraged.



C. Globalization of Clinical Trials

- 1 To encourage the Food and Drug Administration (FDA) to use its existing authority to
- 2 increase monitoring and inspection of foreign clinical trials to ensure the integrity and
- 3 quality of those studies; further,

- 4 To advocate that the FDA expand its oversight of clinical trials conducted abroad by
- 5 continuing to pursue innovative strategies, such as increased collaboration with
- 6 foreign regulatory agencies and changes in domestic regulatory processes that
- 7 support timely submission of foreign clinical trial information; further,

- 8 To encourage the FDA to establish a standardized electronic format and reporting
- 9 standards that would be required for submission of data from foreign clinical trials;
- 10 further,

- 11 To support the ethical treatment of patients in foreign clinical trials in accordance
- 12 with international standards designed to protect human subjects; further,

- 13 To encourage public and private research to study the impact of the globalization of
- 14 clinical trials on patient care.

Rationale

More than 80% of marketing applications for drugs approved in fiscal year 2008 were supported by data from foreign clinical trials, and more than 50% were based on data from trials that were conducted entirely outside of the United States. This trend toward the globalization of clinical trials is expected to continue because of potential benefits to drug manufacturers (e.g., decreased costs, availability of treatment-naive patients). ASHP is concerned that limited experience with clinical trials in some countries could affect data integrity and questioned whether results from foreign clinical trials could always be generalized to patients in the United States because of differences in genetics and cultural factors (e.g., diet, use of supplements). Existing FDA authority allows for oversight of foreign clinical trials, including a requirement for mandatory reporting. However, according to the 2010 Office of Inspector General (OIG) report, [Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials](#), only 0.7 percent of foreign trial investigators were inspected in FY 2008 (compared to 1.9% of investigators in the United States). The FDA should increase oversight of foreign clinical trials given the potential for inconsistencies in protocol implementation and concerns about the availability and integrity of data noted in the OIG report. Development of innovative approaches to expand oversight given limited FDA resources is also encouraged. ASHP supports a recent [FDA agreement with the European Medicines Agency](#) to share information from inspections conducted by that agency and encourages the FDA to establish this type of agreement with other countries, including those whose experience with clinical trials is limited. The FDA should also explore regulatory changes that would support more timely submission of foreign clinical trial information. This recommendation is based on concern that some aspects of current regulations may encourage drug manufacturers to favor foreign clinical trials. For example, submission of an investigational new drug (IND) application triggers FDA oversight, including required submission of clinical trial protocols. Timely submission of an IND is necessary for studies conducted within the United States because it provides an exemption from interstate commerce laws, which is needed to conduct clinical trials. However, interstate commerce laws do not apply abroad. Therefore, there is no requirement or incentive for manufacturers to submit study protocols for foreign trials if they are conducted prior to the IND submission. However, results from those trials are sometimes used to support marketing applications for drug approval. While the FDA can review protocol and data from these studies retrospectively, data omissions and other factors limit the effectiveness of this approach. Earlier submission of this information would enhance the effectiveness of FDA's oversight. Standardization and electronic submission of data from foreign clinical trials should also be encouraged, given the OIG finding that data from these trials was sometimes not available to FDA reviewers. Ethical concerns associated with foreign clinical trials, including documented lapses in informed consent, support the need for improved adherence to ethical standards for conducting clinical research, such as those described in the [International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice](#) and other international guidelines. Finally, the FDA and private entities are encouraged to study the potential patient care impact of the globalization of clinical trials to determine whether there is an impact even when studies are conducted appropriately.

Background

The Council considered the trend of globalization of clinical trials in which studies to support drug approval by the FDA are increasingly being conducted abroad in countries such as China, Asia, Eastern Europe, and Latin America. Benefits of this approach include the availability of treatment-naïve patients and reduced costs. However, questions have been raised about whether there is sufficient FDA oversight of foreign clinical trials, especially in countries with limited experience in conducting this work. In addition, there is concern as to whether the selected patient populations accurately reflect the characteristics of patients in the United States who will be treated with these FDA-approved drugs. The Council's discussion focused on the 2010 Office of Inspector General (OIG) report, *Challenges to the FDA's Ability to Monitor and Inspect Foreign Clinical Trials*, which defined limitations in the FDA's current processes and offered recommendations for improvement. The Council and Board were very supportive of the OIG recommendations, but wished to place additional emphasis on exploring regulatory changes that could improve FDA oversight.

Overall, the Council was supportive of current FDA regulatory requirements that ensure the effectiveness and safety of drug products. However, the Council considered if manufacturers may favor conducting early clinical trials abroad, which can extend patent life by delaying the IND submission. Submission of an IND triggers FDA oversight, including required submission of clinical trial protocols. An IND is necessary for studies conducted within the United States because it provides an exemption from interstate commerce laws. However, interstate commerce laws do not apply abroad. Therefore, there is no requirement or incentive for manufacturers to submit study protocols for foreign trials if they are conducted prior to the IND submission. The Council and Board encouraged the FDA to explore incentives or other strategies to support earlier IND submissions, and in turn, improve availability of information from foreign clinical trials. Other OIG recommendations supported by the Council and Board included the need for a standardized and electronic format for submitting foreign clinical trial data to ensure that it is consistently available and development of innovative strategies to expand FDA oversight, including collaborative agreements with foreign governments to share data from inspections conducted by those entities.

The Council believed that drug manufacturers were ultimately responsible for ensuring the integrity of these trials and noted that no amount of FDA oversight would fully eliminate concerns about study design and implementation. The Board agreed with this assessment. A review of www.clinicaltrials.gov during the Council meeting found 133,000 active trials in 176 countries. Given those numbers, the extent of oversight needed to prevent or eliminate lapses in protocol or misconduct is unattainable. The Council did debate if increased oversight was necessary given that there is limited evidence demonstrating an impact on patient care from the globalization of clinical trials. Some Council members believed that increased oversight was unwarranted, but most agreed that greater enforcement of existing regulations was necessary, even in the absence of evidence of harm. In addition, several examples were provided to illustrate that results from foreign clinical trials are not always directly applicable in the United States. For example, studies to support a new erythromycin-like therapy did not evaluate the drug's activity against a strain of *C. difficile* that is common in the United States. Cultural differences, such as the increased use of dietary supplements or differences in diet, can also impact patient response to therapy and the occurrence of drug interactions. The Council and

Board believed that increased transparency about foreign clinical trials was needed to allow clinicians to better assess how the results should be applied to patients in the United States. In addition, the Council encouraged the FDA and private entities to support evaluations, including postmarketing studies, to assess what, if any, influence these studies had on patient care in this country. The Board supported this recommendation. ASHP was encouraged to provide education to members about the globalization of clinical trials and subsequent application to patient care. Such education could be provided through journal articles, live or web-based education, or in conjunction with partners such as International Pharmaceutical Federation (FIP).

The Council also discussed ethical concerns related to the globalization of clinical trials. A review of published studies conducted in China found that only 18% of reports discussed or provided sufficient information on informed consent processes. The Council believed that peer-reviewed publications should play an enhanced role in ensuring that this information is available. The Council noted that patients often receive financial support for participating in foreign clinical trials. While this support may be nominal by United States standards, it can represent an annual salary in some countries. In addition, in some under developed countries, patients may only gain access to treatment by participating in study protocols. The Council believed that these scenarios place study participants at risk for unethical behavior by study investigators and may influence patient behavior (e.g., lack of adherence), and the Board agreed. Therefore, the Council and Board advocated for improved adherence to ethical standards for conducting clinical research, such as those described in the International Conference on Harmonization Tripartite Guideline for Good Clinical Practice and other international guidelines.



D. Tobacco and Tobacco Products

- 1 To discourage the use and distribution of tobacco and tobacco products in and by
- 2 pharmacies; further,
- 3 To advocate for tobacco-free environments in hospitals and health systems; further,
- 4 To seek, within the bounds of public law and policy, to eliminate the use and
- 5 distribution of tobacco and tobacco products in meeting rooms and corridors at
- 6 ASHP-sponsored events; further,
- 7 To promote the role of pharmacists in tobacco-cessation counseling and medication
- 8 therapy management; further,
- 9 To join with other interested organizations in statements and expressions of
- 10 opposition to the use of tobacco and tobacco products.

(Note: This proposed policy would supersede ASHP policy 0713.)

Rationale

ASHP policy 0713, Tobacco and Tobacco Products, was revised to more clearly define the expanded role of pharmacists in recommending and managing drug therapy to support tobacco cessation, as described in the [ASHP Therapeutic Position Statement on Cessation of Tobacco Use](#). Newer therapies, including varenicline, are associated with more and evolving safety risks when compared to nicotine replacement therapies. Given the complexity of drug therapy, pharmacists should play a central role in ensuring the safe and appropriate use of these therapies. The revisions to this policy better reflect the important role of pharmacists in medication therapy management.

Background

The Council recommended and the Board voted to revise ASHP policy 0713, Tobacco and Tobacco Products, as follows (underline indicates new text):

To discourage the use and distribution of tobacco and tobacco products in and by pharmacies; further,

To advocate for tobacco-free environments in hospitals and health systems; further,

To seek, within the bounds of public law and policy, to eliminate the use and distribution of tobacco and tobacco products in meeting rooms and corridors at ASHP-sponsored events; further,

To promote the role of pharmacists in tobacco-cessation counseling and medication therapy management; further,

To join with other interested organizations in statements and expressions of opposition to the use of tobacco and tobacco products.

The Council and Board believed that this change would better reflect the role of pharmacists in recommending and managing drug therapy to support tobacco cessation. This role has increased dramatically since this policy was introduced. It was noted that newer therapies, including varenicline, are associated with more and evolving safety risks when compared to nicotine replacement therapies. The Council believed and the Board agreed that the increased risks associated with these therapies necessitate greater engagement by pharmacists beyond merely counseling on the benefits of smoking cessation. The Council and Board noted the establishment of FDA oversight of tobacco products as drugs via passage of the Family Smoking Prevention and Tobacco Control Act of 2009. This development, which occurred since this policy was last reviewed in 2007, was viewed favorably.

The Council also discussed the recent introduction of electronic cigarettes, with a focus on the safety risks associated with their use because of harmful chemicals, such as propylene glycol, that have been found in solutions marketed for use with these devices. The Council considered whether additional changes were needed to the policy language to address delivery of the drug via this device. However, a review of recent FDA correspondence indicated that the agency intends to regulate electronic cigarettes as tobacco products, noting that these products

are subject to regulation unless they are marketed as a combination drug/device for therapeutic purposes. Given this intent, the Council believed that the existing verbiage of tobacco products sufficiently addressed this and future devices used to administer the drug. The Board agreed with this assessment. The Council noted that the *ASHP Therapeutic Position Statement on the Cessation of Tobacco Use* would be addressed as part of sunset review in 2012. If continued at that time, the Council suggested that revisions be made to address electronic cigarettes. Education about these drug delivery devices was also recommended via *AJHP*, educational programming, or other communication vehicles.



E. Removal of Propoxyphene from the Market

- 1 To discontinue ASHP policy 0723, which reads:
 - 2 To advocate that the Food and Drug Administration remove propoxyphene
 - 3 from the market because of its poor efficacy and poor safety profile and
 - 4 because more effective and safer alternatives are available to treat mild to
 - 5 moderate pain.

Background

The Council discussed ASHP policy 0723, Removal of Propoxyphene from the Market, as part of sunset review. The Council stated that this policy was no longer needed as a result of the product withdrawal, and recommended that the policy be discontinued. The Board concurred. Activities that led to the withdrawal of propoxyphene from the market in November 2010 were described and the leadership of ASHP in advocating for this action was applauded. The Council played a pivotal role in that work by proposing policy 0723 and developing a guidance document that outlined the evidence demonstrating the poor efficacy and safety profile of the drug and provided recommendations for therapeutic alternatives for the treatment of mild to moderate pain. This guidance was nearing publication when the drug was withdrawn. Therefore, it was not published because it was no longer needed as a result of this action. However, the guidance served as the basis of ASHP advocacy to FDA on this issue. It was noted that propoxyphene and propoxyphene-containing products had previously been the 38th most commonly prescribed drug products in the United States, with a total of 17.5 million prescriptions issued in 2009. Despite this broad use, patient care issues associated with discontinuation of these products were minimized. The success of this transition may, in part, be attributed to drug therapy management provided by pharmacists.

Board Actions

Endorsement of CPIC Guidelines for Cytochrome P450-2C19 (CYP2C19) Genotype and Clopidogrel Therapy

The Council recommended and the Board voted

To endorse the *Clinical Pharmacogenetics Implementation Consortium Guidelines for Cytochrome P450-2C19 (CYP2C19) Genotype and Clopidogrel Therapy*.

The Council reviewed the [Clinical Pharmacogenetics Implementation Consortium Guidelines for Cytochrome P450-2C19 \(CYP2C19\) Genotype and Clopidogrel Therapy](#), which provides guidance on using pharmacogenomic testing to evaluate for variations in cytochrome P450-2C19 (CYP2C19), a liver enzyme that can affect the metabolism of clopidogrel and other drug therapies. The Clinical Pharmacogenetics Implementation Consortium, or CPIC, was formed by the National Institutes of Health's Pharmacogenomics Research Network and the Pharmacogenomics Knowledge Base. The Council recommended and the Board voted to endorse this guidance, noting that it addresses an important need for information on the clinical application of pharmacogenomic testing by providing specific recommendations for interpreting the pharmacogenomic test for CYP2C19 in patients who require antiplatelet therapy. This need for practical guidance was identified in previous Council discussions on pharmacogenomics. The Council and Board appreciated that the guideline did not recommend whether the test should or shouldn't be used, but rather focused on how to interpret the test if it is done. This approach was preferred given ongoing debate about use of the test and barriers to use that include limited access outside of academic medical centers and the extended time frame required to receive results in those settings. The Council stated that lack of evidence demonstrating the cost-effectiveness of the test has also limited its use predominately to high-risk patients (e.g., those who have experienced multiple coronary events) and noted that additional evidence on cost-effectiveness was needed before the test would be used more broadly. The Board agreed with this assessment. In addition to endorsement, ASHP was encouraged to make members aware of the guideline via educational programming or an *AJHP* article that might address the use of this and other pharmacogenomic tests. The Council also provided feedback on the guideline format and content, which will be provided to CPIC to support the development of future guidelines.

ASHP Therapeutic Position Statement on the Treatment of Hypertension

The Council recommended and the Board voted

To discontinue the *ASHP Therapeutic Position Statement on the Treatment of Hypertension*.

The Council reviewed the *ASHP Therapeutic Position Statement on the Treatment of Hypertension* as part of sunset review. This therapeutic position statement (TPS), which was published in 2006, addresses the assertive use of antihypertensive therapies to achieve target blood pressure control in patients with hypertension. The Council stated that inadequate blood

pressure control remains a significant issue. It was noted that Healthy People 2010 called for and achieved blood pressure control in 50 percent of patients with hypertension. While this achievement is commendable, the blood pressure of half of the affected population is still uncontrolled. The Council noted that the TPS—which is based on recommendations in the *Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* and guidelines provided by the National Kidney Disease Education Program and the American Diabetes Association—is outdated, and the Board concurred. However, revision was not recommended until the [*Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*](#) (JNC 8) is released. A draft of that guideline is expected to be available for public comment in late 2011, followed by publication in 2012. The Council recommended and the Board agreed that the current TPS be discontinued for reasons of currency, but advised ASHP to revisit the ongoing need for this guidance following publication of JNC 8. Decision points at that time should include whether ASHP guidance would augment, and not duplicate, guidelines from JNC and other organizations.

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.)

- [Institutional Review Boards and Investigational Use of Drugs](#) (0711)
- [Clinical Investigations of Drugs Used in Elderly and Pediatric Patients](#) (0229)

Other Council Activity

Application of Emerging Drug Safety Information to Clinical Practice

The Council discussed the increasing number of safety issues that arise with drug products following drug approval by the FDA. The extent of new safety information found in the medical literature and in safety warnings issued by MedWatch is useful, but these messages often raise questions without providing clear answers on how the information should be applied to individual patient care. This is especially true of MedWatch notices that are issued in response to early signals of serious risk identified in the Adverse Drug Event Reporting System (AERS) database. As described by the FDA, these messages indicate a potential safety issue, but one that has not been definitively identified as caused by the drug and therefore the subject of ongoing review by the FDA.

The Council stated that there are significant challenges in applying emerging safety information to clinical practice, including assessing the clinical significance of the safety concern, evaluating the correlation between the drug and the safety risk, and determining and implementing proposed actions. The Council estimated that each MedWatch notice requires between 2 and 10 hours to assess and implement depending on the type and severity of the safety concern. Evolving safety messages based on early safety signals are especially problematic in terms of deciding whether, when, and what changes are needed related to use of the drug within the facility. These decision points often lead to inconsistencies in how

messages are applied at different facilities within one health system and among different health systems. To address these challenges, the Council recommended that ASHP develop a guidance document that would describe the recommended steps that health systems should follow when managing these safety messages. The goal of the guidance would be to increase standardization and ensure the safety of drug use. The Council also encouraged drug information providers, software vendors, and group purchasing organizations to provide information and resources to assist in this process whenever possible. ASHP was encouraged to make members aware of a publicly accessible web site offered by the University of Utah Drug Information Service (<http://healthcare.utah.edu/pharmacy/alerts/>) that provides guidance on the implementation of specific MedWatch notices.

The Council believed that existing work in this area by the FDA was very good, but offered several suggestions to enhance the usefulness of MedWatch messages. These suggestions, which include providing information about the specific studies that generated the warning and data on the number of safety reports compared to the extent of drug use in the overall population, will be shared with FDA staff. Development of a rating scale to identify warnings of highest importance was also suggested. While the intent of MedWatch notices is to prevent harm, the Council believed that these messages frequently generate undue fear in patients when they are taken out of context or over-emphasized by traditional or social media sources. Simultaneous and broad dissemination to all audiences often precipitates immediate phone calls to pharmacists and other clinicians before information resources are available to address patient concerns. It was noted that ASHP's *American Hospital Formulary Service (AHFS)*, which serves as the drug information source for LexiComp and other databases used in the inpatient and outpatient settings, includes this information within 24 hours of receiving the MedWatch notice. The Council encouraged FDA to provide this information to *AHFS* and other drug information providers just prior to public release under an embargo agreement that would facilitate more rapid dissemination of the information and ensure that it is available when it is most needed at the point of patient care (i.e., within the first several days of the announcement).

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

The Council reviewed the [ASHP Therapeutic Position Statement on the Use of Second-Generation Antipsychotic Medications in the Treatment of Adults with Psychotic Disorders](#) as part of sunset review. This TPS, which was published in 2007, addresses the appropriate use of second generation antipsychotics as first-line treatment for psychotic disorders. Discussion focused on new effectiveness data as well as strategies to prevent side effects associated with these therapies, including metabolic syndrome and sudden cardiac death. The Council noted that management of these therapies is complex and requires attention to differing cognitive effects, dosing, and monitoring for side effects and effectiveness as compared to first-generation antipsychotics. The Council strongly believed that pharmacists can and should play a central role in managing these therapies. Therefore, the Council stated that this guidance was still relevant and voted to revise it. Suggested revisions include updating the guidance to include more recent data on effectiveness and strategies for proactive monitoring of patients

with cardiovascular risks to prevent side effects. A brief discussion of pharmacy resources necessary to manage these therapies was recommended. It was also suggested that the guideline be expanded to evaluate the evidence for use of second-generation antipsychotics to treat other conditions, including depression, post-traumatic stress disorder, insomnia, and agitation or delirium in the emergency room or intensive care setting.

Evaluation of Proposed Models for Print Direct-to-Consumer Advertising

The Council reviewed a recent FDA-conducted study of proposed models for print direct-to-consumer (DTC) advertising. New formats have been proposed to improve the required brief summary, which is intended to provide information on a drug's side effects, contraindications, and effectiveness. FDA regulations state that print advertising must provide a brief summary of side effects, contraindications and effectiveness information from the approved product labeling. Current approaches for including this information include reprinting relevant sections of the prescribing information (PI) or reprinting the entire PI. The Council stated that neither approach supports informed decision-making by patients. There was strong agreement that these advertisements cannot stand alone and need to be supplemented by discussions between the patient and their clinicians.

The Council reviewed the proposed print models in the context of existing [ASHP policy 1119, Direct-to-Consumer Advertising of Prescription and Nonprescription Medications](#), which opposes DTC advertising unless it meets certain requirements. Four models were evaluated using a hypothetical drug for weight loss. Models included the traditional format, an abbreviated version that highlighted required information, a question and answer format, and a drug facts box intended to mirror the format used for nonprescription products. The study, which surveyed 300 volunteers recruited in a shopping mall, found that participants favored the drug facts box. The question and answer format was the second most preferred format.

The Council appreciated the familiarity and brevity of the drug facts box, but questioned if all relevant information could be provided in this abbreviated format. There was also some concern that this format would cause patients to be confused about whether a product was available as a nonprescription product or by prescription only. A perceived benefit of the question and answer format was delivery of information in a format that is actionable. An approach that would combine the drug facts box and question and answer format was recommended by some Council members. The Council appreciated FDA's efforts to improve print DTC advertising, but recommended that the Agency conduct additional studies of these formats using information from an FDA-approved product instead of a hypothetical drug product. The Council also questioned whether recruitment of patients at a shopping mall might bias selection to individuals of higher socioeconomic status. Studies to evaluate the advertisements' affect on actual drug use and patient outcomes, in addition to format preference and comprehension, would also be beneficial. The Council believed that any of the proposed formats was an improvement compared to the existing approach. Therefore, the Council was not opposed to implementation of a proposed model while additional research is conducted.

Safety and Effectiveness of Proposed Nonprescription Status for Oral Contraceptives

The Council considered the implications on safety and effectiveness if oral contraceptives were made available as nonprescription therapies. With the intent of reducing unwanted pregnancies, the Reproductive Health Technologies Project Working Group on Oral Contraceptives (a private women's health clinical and research group) and others have called for broader access to these therapies via a nonprescription progestin-only formulation. It was noted that in early 2011, [Changing Oral Contraceptives to Over-the-Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy](#) was published in *Pharmacotherapy*. That statement supports nonprescription status of progestin-only and estrogen-progestin combination oral contraceptive products if certain conditions are met, including availability only through licensed pharmacies while a pharmacist is available for consultation and Medicaid coverage. The statement had not been considered for endorsement by the American College of Clinical Pharmacy Board of Directors at the time of the Council's discussion.

The Council discussed progestin-only and combination oral contraceptive products in the context of FDA's criteria for nonprescription status—which include that the benefit of use must outweigh the risk, ability of patients to self diagnose, provision of adequate labeling, and no need for guidance from a health care professional to ensure proper use. The Council could not reach consensus on whether all of these conditions were met. The debate focused on an assessment of the risk versus benefit of making these products available without a prescription. The Council did agree that there was a significant difference in safety and effectiveness profiles when comparing progestin-only and combination oral contraceptive products. It was noted that combination products are effective and easy to use, but are associated with more adverse events. Progestin-only products are generally safer for most patients, but are contraindicated for some, including those with liver disease or breast carcinoma. Progestin-only products can also be less effective if patients do not closely adhere to directions for use (e.g., consistent timing of administration). It was noted that progestin-only products are not considered first-line therapy and the need for screening and follow-up by a health care professional would likely tip the balance toward these products being inappropriate for nonprescription status. Related to self-diagnosis, the Council stated that smoking history, high blood pressure, and cardiovascular disease are important screenings for both product types. A majority of Council members were encouraged by studies showing that most patients were able to appropriately self-screen for contraindications to oral contraceptives. However, other Council members expressed concern that almost 7 percent of patients did not correctly self-screen for contraindications in one study. The Council also considered arguments against nonprescription status that assert that this access would dissuade women from having routine gynecological exams. These appointments often serve as a gatekeeper for prescriptions for oral contraceptives. The Council rejected this argument, noting that oral contraceptives should not be used to mandate health care visits. It was noted that oral contraceptives are effective if used appropriately and that laboratory monitoring is not needed for these products, with the exception of those that contain drospirenone, which can alter potassium levels. These factors could support

nonprescription status, but Council members remained concerned about whether the benefits outweighed the potential risks.

The Council believed that pharmacists could play a role in screening and monitoring related to the use of these therapies, but expressed concern about workload and lack of reimbursement for these services. The Council also raised several practical concerns about nonprescription status for oral contraceptive products. Documentation of the use of oral contraceptives in the patient's medication profile was considered necessary to ensure proper screening for interactions with antibiotics and other drugs. It was noted that this documentation is more challenging for nonprescription products, which patients may obtain from multiple pharmacies. Liability for pregnancies resulting from inappropriate use of a nonprescription or intermediate category product was another concern. The Council also debated whether current access to these therapies is truly insufficient, noting that oral contraceptives are widely available through Planned Parenthood and other free clinics. There was concern that nonprescription status would actually increase patient costs as was seen when nonsedating antihistamines gained nonprescription status.

The Council did not reach consensus on whether oral contraceptives were safe and effective for nonprescription use. Therefore, it was requested that ASHP continue to monitor developments, including tracking the stances of other health care professional associations. The Council wished to revisit this topic when more information becomes available.

Factors Affecting a Medication Complexity Index

The Council provided guidance in advance of an expert panel that will be convened by ASHP and the ASHP Research and Education Foundation to develop a medication complexity index. The need for this index is based on a recommendation from the Pharmacy Practice Model Initiative Summit that "all patients should have a right to receive the care of a pharmacist." Summit participants recognized that limited pharmacist resources need to be allocated based on the complexity of patient needs and health system characteristics. Therefore, development of a medication complexity index that could be used to prioritize patients that should receive pharmacist-provided drug therapy management was requested. The Council discussion focused on clinical and practice factors that should be considered in developing that index.

The Council noted that nursing has developed indices that have been shown to improve patient outcomes and reduce health care costs. These models are usually based on patient acuity and include factors such as the type of medical procedure performed, use of "complicated" intravenous drugs, and the overall number of medications. These and other indices, such as the case mix index that focuses on costs associated with Diagnosis Related Groups, are generally not appropriate to allocate pharmacy services because these methods do not correlate well with the complexity of drug therapy. For example, a post-operative patient may require intense nursing care but only receive two or three medications that require limited intervention by a pharmacist. On the other hand, a patient admitted for exacerbation of congestive heart failure may not be targeted using nursing indices, but would benefit from pharmacist-provided medication therapy management to improve chronic disease management.

The Council believed that the type and number of medications is an important factor for development of the index. Medications targeted for intervention might include those that require titration, self-administration, or self monitoring. While a medication focus may be a likely starting point, the Council strongly encouraged the expert panel to consider quality measures and reimbursement policies, including those related to readmissions and health-care acquired conditions, when developing the index. The Council discussed the distinction between an index based on medication complexity and one based on patient complexity, which would assess need based on drug therapy and other factors that determine if patient outcomes are amenable to pharmacist interventions. These factors include, but are not limited to, disease severity, disease control, and the number and type of concomitant conditions. The Council highlighted that medication use can also be influenced by non-disease- and non-drug factors, such as health literacy, socioeconomic status, and availability of a family or other support structure.

Desirable characteristics of a medication complexity index include a tool that is simple, but also adaptable and applicable across various health care settings. While the tool should be predominantly based on objective data, the Council advised that its use should allow for subjective interpretation. Ease of use and time to implement are key factors to aid adoption. The Council suggested a format similar to the point system established in the CHEST guidelines. The Council also discussed timing for use of the tool. At admission was considered an ideal time, but transitions of care are also critical. The Council considered whether the index would be applied differently in patients in critical condition versus those preparing for hospital discharge and questioned whether one index would meet both needs.

Board Certification for Pharmacists

The Council discussed the new business item, “Board Certification for Pharmacists,” that was submitted by the Section of Clinical Specialists and Scientists during the 2011 ASHP House of Delegates. The New Business Item was referred by the House, approved by the ASHP Board of Directors in January, and is being considered by the House. The Council was asked to review and comment on the clinical and practice impact of the New Business Item, with the intent of informing those discussions. The Council was largely supportive of the New Business Item, which states that all pharmacists who practice in specialty areas should be certified, if such certification exists. Overall, this was viewed favorably as a future vision for pharmacy practice. The Council’s discussion focused on the time line and process for expanding certification, including how it would implemented at the practice level (e.g., hiring requirements, continuing professional development).

The Council strongly supported the need to establish a baseline credential that would be applicable across patient populations and settings. This was considered important to minimize calls for sub-specialties that may not have adequate demand or resources to justify a stand-alone credential. In terms of determining and prioritizing future specialties, in addition to the factors described in the policy, the Council believed it was important to consider the number of available residencies as this would indicate a pipeline of expertise to both develop and take the exam. The need for a specialty credential in pharmacy management was noted, whether this was provided via BPS or an organization such as the American College of Healthcare Executives.

In general, the Council supported standardization of eligibility requirements, but questioned whether there might be some specialties for which minor variation was desirable based on patient care needs. In addition, some Council members expressed concern that the proposed standardization of eligibility requirements included completion of postgraduate year 2 residency program. This concern was based on the limited number of residencies in some specialty areas. The Council was reminded that the proposed policy was intended as a future vision for pharmacy practice and that an increase in the number of specialized residencies was projected.



SEIZE THE INITIATIVE

ASHP House of Delegates 2012
June 10 and 12, 2012

Policy Recommendation from the Section of Clinical Specialists and Scientists



Board Certification for Pharmacists

- 1 To support the principle that pharmacists who practice where a pharmacy specialty
- 2 has been formally recognized by the profession should become board certified in the
- 3 appropriate specialty area; further,

- 4 To recognize the Board of Pharmacy Specialties (BPS) as an appropriate organization
- 5 through which specialties are formally recognized and specialty pharmacy
- 6 certification should occur; further,

- 7 To advocate prioritization for recognition of new specialties in those areas where
- 8 sufficient numbers of postgraduate year two residency training programs are
- 9 established and where adequate numbers of pharmacists are completing accredited
- 10 training programs to prepare them to practice in the specialty area; further,

- 11 To advocate for standardization of credentialing eligibility and recertification
- 12 requirements to include consistent requirements for advanced postgraduate
- 13 residency training; further,

- 14 To promote a future vision encouraging accredited training as an eventual
- 15 prerequisite for board certification; further,

- 16 To encourage BPS to be sensitive to the needs of current practitioners as
- 17 prerequisites evolve; further,

- 18 To actively encourage and support the development of effective training and
- 19 recertification programs that prepare specialists for certification examination and
- 20 ensure the maintenance of core competencies in their area of specialization.

Rationale

As medication therapies become more complex, the need for specialized expertise increases. Some areas of health care practice evolve to the point where certification, based on formal accredited training and psychometrically valid examination, is needed to assure the public and other health care professionals of a level of competence, quality, and consistency among specialists practicing in that field. Certification, as defined by Council on Credentialing in Pharmacy, is the process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization. Formal recognition of pharmacy specialties demonstrates the unique knowledge, skills, and abilities of pharmacists in well-defined areas of practice and provides the assurance the public and other health care professionals need.

ASHP has long recognized the value of specialty certification. ASHP has been involved in four of the six petitions to the Board of Pharmacy Specialties (BPS) requesting recognition of new pharmacy specialties. ASHP was the sole petitioning organization for two specialties, and has worked jointly with other organizations in developing two other specialties. The *ASHP Long Range Vision for Pharmacy Work Force in Hospitals and Health Systems* states that pharmacists who provide services in an area where specialty certification exists should be certified in that specialty, and the *ASHP Supplemental Standards for Postgraduate Training* require such certification of residency program directors only. More recently, the Pharmacy Practice Model Initiative (PPMI) recommended that pharmacists who provide drug therapy management should be certified through the most appropriate BPS board-certification process if such a specialty has been established (Recommendation B10).

BPS is currently the only pharmacist-certifying organization accredited by the National Commission for Certifying Agencies (NCCA). NCCA accreditation ensures very high quality standards in the professional certification industry. Although other organizations have developed an array of credentials of differing value, those credentials do not necessarily represent the recognition of a unique area of specialization and the development of processes recognized by the profession to ensure the quality of specialty practice. It is also important to distinguish the recognition of specialties within the practice of pharmacy from other multidisciplinary certifications. Although some similarities exist in the nature of such programs, they also do not represent the recognition of a unique area of specialization and the development of processes recognized by the pharmacy profession to ensure the quality of specialty practice.

The profession should be more strategic in its efforts to grow and mature new specialties. To date, the pharmacy profession has relied upon an episodic petitioning process to identify and recognize new specialties. A methodical specialty development process would prioritize recognition of areas of practice for which a sufficient number of high-quality training programs exist and would promote development of training programs in emerging areas of pharmacy specialization in advance of specialty recognition.

Eligibility requirements for Board certification vary widely among currently recognized specialties. Although it may not currently be possible to require residency training as a prerequisite for all BPS specialty certification applicants, over time postgraduate year two residency training should become the preferred prerequisite to establish consistent requirements across specialties and provide a stronger linkage between training and

certification. ASHP policy currently supports the principle that accredited training is an important future prerequisite for pharmacy technicians prior to certification by the Pharmacy Technician Certification Board. This same principle that accredited training should precede certification should also apply to specialists in our profession. It will be important for BPS to plan for this future vision and evolve requirements in a manner that is sensitive to the needs of existing practitioners.

Background

In 2011, the House of Delegates approved a new business item from the Section of Clinical Specialists and Scientists concerning BPS certification. Following the House session, the Section solicited feedback from members and ASHP councils to draft final policy recommendation language, which was amended and approved by the Board at its January meeting.



SEIZE THE INITIATIVE

ASHP House of Delegates 2012
June 10 and 12, 2012



ASHP Statement on Use of Social Media by Pharmacy Professionals

Position

- 1 The American Society of Health-System Pharmacists (ASHP) encourages pharmacy
2 professionals working in hospitals and health systems to use social media in a professional,
3 responsible, and respectful manner to complement and enhance their relationships with
4 patients, caregivers, other members of the health care team, and the public. To achieve that
5 goal, pharmacy professionals should
- 6 • thoroughly consider the purposes and potential outcomes of participation in social
7 media and develop the strategies and skills required to effectively utilize social
8 media to meet their goals, and
 - 9 • exercise professional judgment and adhere to professional standards and legal
10 requirements in both private and public social media communications, especially
11 legal and ethical obligations to protect the privacy of personal health information.

Background

12 The term “social media” may be defined as online tools that allow interaction among
13 individuals. Examples include professional networks such as ASHP Connect, career-building
14 networks such as LinkedIn, and sites such as Facebook and Twitter that are primarily social
15 but which may serve multiple purposes.¹⁻³ Informational sites regarding medical information
16 that allow for commentary from users and medical professionals (e.g., PharmQD, The
17 Pharmacist Society, Sermo) should also be considered collaborative social media.

18 Social media have transformed the way people communicate by reducing barriers to
19 the exchange of information, increasing both the amount of communication and the
20 number of people who can participate. Health care organizations (e.g., hospitals, health
21 systems, professional societies, pharmaceutical companies, patient advocacy groups, and
22 pharmacy benefit companies) have chosen to use social media for both communication and
23 marketing.

24 Like other health care professionals, pharmacy professionals have adapted to
25 advancing technology and are using social media to communicate with patients, caregivers,
26 other health care professionals, and the public. Pharmacy professionals (including pharmacy
27 students, as professionals in training) should continue to incorporate these new tools into
28 the armamentarium of pharmacy practice and apply them with professional judgment to
29 pursue the goal of helping people make the best use of medications. Social media provide
30 pharmacy professionals with opportunities to educate patients and practitioners, seek
31 advice from and provide advice to colleagues, optimize the medication use of individual
32 patients and populations, promote the role of pharmacists in caring for patients, and
33 engage in debate about issues in health care practice and policy, among other things.¹⁻⁵

Participation in Social Media

34 Hospitals or health systems that choose to use social media or permit practice-related social
35 media use by staff should have in place policies and procedures that

- 36 • balance the benefits social media provide with the obligations and liabilities they
37 may create, and
- 38 • encourage the development and application of best practices by users of social
39 media.

40 The details of such policies, procedures, and best practices are beyond the scope of this
41 statement, which has as its purpose to briefly outline some of the considerations that
42 should guide pharmacy professionals' participation in social media.

43 Pharmacy professionals should carefully consider the purposes and potential outcomes
44 of their participation in social media and develop the strategies and skills required to
45 achieve their goals. They need to be aware of and employ best practices when using social
46 media, because health care practitioners, including pharmacy professionals, are held to a
47 higher standard of professionalism within and outside the workplace than members of the
48 public.⁶ Pharmacy professionals who participate in social media should strive for a high
49 degree of professionalism in their communications and ensure that patient privacy is not
50 compromised.

Professionalism

51 ASHP has long advocated for the adoption of high professional aspirations for pharmacy
52 practice. Pharmacists' responsibilities as professionals include "advancing the well-being
53 and dignity of their patients, acting with integrity and conscience, [and] collaborating
54 respectfully with health care colleagues."⁷ The following recommendations for the use of
55 social media represent high professional aspirations, and pharmacy professionals are
56 encouraged to exercise their professional judgment in incorporating them into their
57 practices.

58 **Advancing the well-being and dignity of patients.** The following recommendations can
59 help pharmacy professionals who choose to participate in social media advance the well-
60 being and dignity of patients.

- 61 1. Medical advice offered through social media should be provided in accordance with
62 the professional standards of pharmacy practice. For example, pharmacy professionals
63 should provide medical advice only with a complete understanding of the patient's
64 medical conditions and only if they accept the associated liabilities, especially those
65 regarding privacy and the requirements of pharmacy practice. Pharmacy professionals
66 should be aware that providing medical advice may create a pharmacist-patient
67 relationship, with all its attendant obligations and liabilities. All online relationships
68 should conform to the ethical boundaries of an appropriate patient-pharmacist
69 relationship.⁸
- 70 2. Pharmacy professionals should be cognizant of both the benefits and limitations of
71 online communication. Social media may serve especially well as a point of initial
72 contact or as a convenient way to maintain contact between patients and care
73 providers, but professionals must recognize when a patient's health care needs would
74 be better met through other means (e.g., phone consultation or an office visit).
- 75 3. Pharmacy professionals should view social media as a means to not only provide timely
76 and accurate drug information but also to rebut inaccurate, misleading, or outdated

77 information. While the purpose of specific social media content may not always be
78 apparent, pharmacy professionals also need to be aware of and alert to the use of
79 social media for marketing and sales purposes.

80 4. Complaining about or disparaging patients, even in general terms, does not advance
81 the dignity of patients or the profession. Communications that contain patients’
82 identifying information would violate privacy requirements, which are discussed in
83 more detail below. Pharmacy professionals should keep in mind that simply avoiding
84 the name of a patient may not be sufficient to avoid patient identification.

85 **Acting with integrity and conscience.** The following recommendations are intended to
86 assist pharmacy professionals to act with integrity and conscience in their use of social
87 media.

88 1. Pharmacy professionals should carefully distinguish between personal and
89 professional information within social media and make conscientious decisions
90 regarding who will have access to personal or professional information. Although some
91 organizations recommend use of a strictly personal and a separate, strictly practice-
92 related page,⁹ professionals will quickly recognize the difficulty of making such
93 distinctions. The higher standards of conduct expected of professionals, even in
94 personal behavior, apply as well to their participation in social media.^{6, 10}

95 2. Pharmacy professionals must be conscious that content posted to social media may
96 have consequences on reputations or careers for years to come, reflect poorly upon
97 the pharmacy profession, or undermine patient confidence in the care provided.
98 Postings on social media should be subject to the same professional standards and
99 ethical considerations as other personal or public interactions.

100 3. The apparent anonymity provided by social media does not release pharmacy
101 professionals from their ethical obligation to disclose potential conflicts of interest,
102 especially when representing themselves as professionals. Some circumstances may
103 require personal identification or disclosure of potential competing interests.⁹

104 4. Although all pharmacists should use social media in ways that set positive examples
105 for pharmacy students and residents, preceptors and mentors have a special
106 responsibility to model appropriate practices.^{7,11}

107 **Collaborating respectfully with health care colleagues.** Although social media can and
108 should be used to promote healthy debate about health care and pharmacy practice, such
109 debate should be conducted in a respectful manner. Reasoned debate sometimes requires
110 constructive criticism, but pharmacy professionals should not use social media to make ad
111 hominem comments or needlessly denigrate specific care providers, institutions, or
112 professions.

Patient Privacy

113 Health care professionals have long confronted the challenge of “communicat[ing] freely
114 with each other while maintaining patient confidentiality and privacy.”¹² Social media, by
115 their very nature, present new issues of privacy and confidentiality by extending the reach
116 of communications. The following recommendations may help pharmacy professionals
117 protect patient privacy and confidentiality as they navigate this new terrain.

118 1. Pharmacy professionals should continue to adhere to all laws, regulations, standards,
119 and other mandates intended to protect patient privacy and confidentiality in all
120 environments, including social media.⁸

- 121 2. Pharmacy professionals should exercise professional judgment and employ established
 122 best practices to ensure compliance with privacy requirements when communicating
 123 with patients or about specific patient cases on social media.^{9, 13, 14}
 124 3. Pharmacy professionals should select privacy settings in social media accounts that
 125 provide the greatest degree of protection for personal information, keeping in mind
 126 that privacy settings are not perfect and that information posted online is likely
 127 permanent. Continuous self-monitoring of privacy settings is necessary, as social
 128 media sites change privacy policies.¹⁰

Conclusion

129 Social media are emerging as important modes of communication and are increasingly
 130 being used for personal, professional, and business communication, as well as for patient
 131 care. As medical professionals held to high standards of personal, professional, ethical, and
 132 moral conduct, pharmacy professionals have a responsibility to use social media
 133 appropriately.

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Background

In 2010, the Council on Pharmacy Practice noted the growing use of social media by pharmacy professionals and discussed its benefits and risks. The Council recommended that the Pharmacy Student Forum consider developing guidance on the topic. The Executive Committee of the Pharmacy Student Forum began work on an ASHP statement in 2011, and with the assistance of members of the Section of Pharmacy Informatics and Technology, a draft was completed by November 2011. The draft was revised in response to comments from more than 25 ASHP members and subsequently approved by the executive committees of the Pharmacy Student Forum and the Section of Pharmacy Informatics and Technology and by the Board of Directors.