

House of Delegates

AGENDA

2017 ASHP

Regional Delegate Conferences

Note: **Day One** runs from 1:30 to 5:30 p.m., followed by dinner from 7:00 to 9:00 p.m. The agenda is completed on **Day Two**, which runs from 8:30 to 11:00 a.m.

Day One

- A. Welcome and Introductions
- B. Regional Delegate Conference (RDC) Objectives
- C. Review of RDC Agenda
- D. Responsibilities of Delegates
- E. Characteristics of Good Policy and Substantive Amendments
- F. Summary of Virtual House of Delegates
- G. Review of Policy Recommendations and Resolution
- H. Dinner

Day Two

OPTIONAL SESSION ON HOUSE OF DELEGATES PROCEDURES (8:00 - 8:30 a.m.)

- A. Review of Remaining Policy Recommendations and Resolution
- B. Treasurer's Report
- C. ASHP Building Update
- D. Open Discussion
- E. Keeping the Discussion Going Via ASHP Connect and at State Affiliate Meetings

F. Important Events for Delegates

1. Summer Meetings Registration
 - Delegates and Alternate Delegates to the House must register to attend one of the [four Summer Meetings](#). (Registrants may attend sessions of any meeting.)
2. House of Delegates Registration
3. Open Forum for Members
4. Delegate Primer on House of Delegates Processes (open to all delegates)
5. First Delegate Caucus*
6. Other Caucuses -- Small and Rural; Federal Pharmacists
7. First House of Delegates Meeting*
8. ASHP-PAC Donors Reception
9. Meet the Candidates
10. Delegate Reception
11. Second Delegate Caucus*
12. Second House of Delegates Meeting*
13. Collecting Information from and Reporting to Constituents on the RDC and House
14. November Virtual House of Delegates Meeting

**Attendance at these events is an expectation of delegate service.*

G. Evaluation of the RDC

H. Adjournment

House of Delegates

AGENDA

**ASHP House of Delegates
Minneapolis, Minnesota**

**Presiding – Amber J. Lucas
Chair, House of Delegates**

FIRST MEETING

**Minneapolis Convention Center
Sunday, June 4, 2017
1:00 – 5:00 p.m.**

1. CALL TO ORDER
2. ROLL CALL OF DELEGATES
3. REPORT ON PREVIOUS SESSION
4. RATIFICATION OF PREVIOUS ACTIONS
5. COMMITTEES OF THE HOUSE
 - a. REPORT OF COMMITTEE ON NOMINATIONS
6. COMMITTEES OF THE BOARD
 - a. REPORT OF COMMITTEE ON RESOLUTIONS
7. REPORT OF TASK FORCE ON ASHP POSITION ON MEDICAL AID IN DYING
Lisa M. Gersema, ASHP President
8. BOARD OF DIRECTORS REPORTS
 - a. COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT
Todd A. Karpinski, Board Liaison
 - b. COUNCIL ON PHARMACY MANAGEMENT
Timothy R. Brown, Board Liaison
 - c. COUNCIL ON PHARMACY PRACTICE
Jennifer M. Schultz, Board Liaison
 - d. COUNCIL ON PUBLIC POLICY
Ranee M. Runnebaum, Board Liaison
 - e. COUNCIL ON THERAPEUTICS
Donald E. Letendre, Board Liaison
9. REPORT OF THE TREASURER

10. RECOMMENDATIONS OF DELEGATES
11. ANNOUNCEMENTS
12. ADJOURNMENT OF FIRST MEETING

SECOND MEETING

Minneapolis Convention Center
Tuesday, June 6, 2017
4:00 – 6:00 p.m.

1. CALL TO ORDER
2. QUORUM CALL
3. RESOLUTION
4. REPORTS OF OFFICERS
 - a. PRESIDENT AND CHAIR OF THE BOARD
Lisa M. Gersema
 - b. CHIEF EXECUTIVE OFFICER
Paul W. Abramowitz
5. UNFINISHED AND NEW BUSINESS
6. RECOMMENDATIONS OF DELEGATES
7. INSTALLATION OF OFFICERS AND DIRECTORS
8. ANNOUNCEMENTS
9. ADJOURNMENT OF SECOND MEETING



Board Report on the Joint Council Task Force on Pharmacist Participation in Medical Aid in Dying

Pharmacist Participation in Medical Aid in Dying

- 1 To affirm that a pharmacist's decision to participate or decline to participate in medical aid
- 2 in dying for competent, terminally ill patients, where legal, is one of individual conscience;
- 3 further,
- 4 To reaffirm that pharmacists have a right to participate or decline to participate in medical
- 5 aid in dying without retribution; further,
- 6 To take a stance of studied neutrality on legislation that would permit medical aid in dying
- 7 for competent, terminally ill patients.

(Note: This policy would supersede ASHP policy 9915.)

Rationale

Medical aid in dying (also called physician-assisted dying, physician-assisted suicide, physician aid in dying, physician-assisted death, hastened death, medically assisted dying, and death with dignity) has been legal in some areas of the U.S. since Oregon passed its Death with Dignity Law in 1995. By 2016, one sixth of U.S. citizens lived in a jurisdiction in which medical aid in dying was available, and more states were contemplating legislation to legalize it. Experience in Oregon and elsewhere demonstrates that pharmacists in those jurisdictions may be confronted with the difficult ethical question of whether to participate in medical aid in dying.

For purposes of this policy position, ASHP adapts [a common definition of medical aid in dying](#): the practice in which a physician provides a prescription for a lethal dose of medication to a terminally ill, competent patient at the patient's request that the patient can self-administer at a time of his or her choosing to end his or her life. ASHP notes that many of the terms commonly used to describe this practice ignore the patient care and dispensing roles of pharmacists as well as the roles of other healthcare professionals, such as hospice nurses, in providing care for patients requesting medical aid in dying. ASHP recognizes the utility of a term

such as “medical aid in dying” that addresses the roles of all healthcare providers involved in or affected by the practice but acknowledges the term’s ambiguity regarding self-administration of the lethal dose. ASHP therefore explicitly distinguishes medical aid in dying from all forms of euthanasia, which is not the subject of this policy.

ASHP takes a position of studied neutrality on whether pharmacists should participate in medical aid in dying. Studied neutrality has been defined as “the careful or premeditated practice of being neutral in a dispute” and has as its goals “to foster a respectful culture among people of diverse views and to guide action that does not afford material advantage to a [particular] group.” (Johnstone M-J. [Organization Position Statements and the Stance of “Studied Neutrality” on Euthanasia in Palliative Care](#). *J Pain Symp Manag*. 2012; 44:896-907.) ASHP respects the diversity of views of its members and other pharmacists on medical aid in dying and adopts a position of studied neutrality to promote patient autonomy and access to care and to protect pharmacists’ professional integrity and comity.

The [Code of Ethics for Pharmacists](#) states that “a pharmacist promises to help individuals achieve optimum benefit from their medications [and] to be committed to their welfare” and that “a pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health.” In pharmacist decision-making about participation in medical aid in dying, those principles may clash. Self-determination dictates that patients should be free to exercise their ethical and legal right to choose or decline any legally available treatment. Many healthcare professionals, and their organizations (including the [American Medical Association](#), the [American College of Physicians](#), and the [American Nurses Association](#)), question whether death is ever an acceptable therapeutic goal. Others (including the [American Academy of Hospice and Palliative Medicine](#) and the [American Psychological Association](#)) acknowledge in their statements of neutrality that society may determine that medical aid in dying falls within a spectrum of treatments and withholding of treatments that has as its goal the relief of suffering through a compassionately hastened death, even while recognizing the risks of such a practice.

Pharmacists, like other healthcare professionals, have a right to examine and act on the moral and ethical issues involved in providing care to patients. ASHP policy position 0610, [Pharmacist’s Right of Conscience and Patient’s Right of Access to Therapy](#), outlines the rights and responsibilities of pharmacists and other pharmacy employees who decline to participate in therapies that they find morally, religiously, or ethically troubling, including the right to reasonable accommodation of their right to conscience in a nonpunitive manner. Procedures should be in place to ensure that healthcare organizations can provide mission-compatible care to patients, and that healthcare providers practicing there are not a barrier to the organization’s ability to provide that care. In adopting its position of studied neutrality on pharmacist involvement in medical aid in dying, ASHP recognizes that adopting a position in favor of participation would infringe on the moral and ethical prerogatives of pharmacists. ASHP similarly recognizes that a stance against participation would make the same infringement and in addition present the risk of legal or professional sanction for pharmacists who participate in medical aid in dying where it is legal.

ASHP also takes a position of studied neutrality on whether medical aid in dying should be legally permitted for competent, terminally ill patients. ASHP recognizes that society may interpret the principle of patient autonomy to include the right to therapies that some may find

morally, religiously, or ethically troubling, including medical aid in dying. Recognizing as well the role of healthcare professionals as guardians against practices that would undermine patient autonomy, ASHP advocates that, when permitted, medical aid in dying only be available to competent, terminally ill patients who freely and knowledgeably make that choice.

ASHP joins other healthcare professional organizations in noting that medical aid in dying is inextricably linked with hospice, palliative, and other end-of-life care. ASHP will therefore continue to advocate that patients receive appropriate pharmacist care at the end of life, including [pain management \(ASHP policy 1106\)](#), [support in dying \(ASHP policy 0307\)](#), and [hospice and palliative care](#).

Background

In June 2016, the ASHP House of Delegates considered a [resolution](#), ASHP Position on Assisted Suicide, and voted to refer the resolution to the appropriate ASHP committee, as determined by the Board of Directors, for further study. The Board of Directors convened the Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy as a Joint Council Task Force to consider ASHP policy 9915, [ASHP Position on Assisted Suicide](#), and the [ASHP Statement on Pharmacist Decision-making on Assisted Suicide](#). The charge of the Joint Council Task Force was to review existing ASHP policy on assisted suicide and recommend to the Board of Directors what ASHP's official stance should be on the following questions:

- 1) Should ASHP reaffirm (through its current policy) that the decision to participate in the use of medications in assisted suicide is one of individual conscience, or should ASHP encourage or discourage pharmacist participation in dispensing medications for use in the suicide of terminally ill patients?
- 2) Based on the recommendation made regarding question 1 above, determine whether the guidance offered in the ASHP Statement on Pharmacist's Decision-making on Assisted Suicide is current, relevant, and complete. More specifically, does the statement appropriately address the following issues:
 - The practitioner's duty to care for the patient and caregiver vis-a-vis palliative care.
 - The practitioner's right to refuse to participate in treatments that are morally, religiously, or ethically troubling.
 - The practitioner's responsibility to the employer in the context of employment law.
 - The employer's responsibility to provide care to the patient.
 - The employer's responsibility to provide services to the patient's caregiver.

The Task Force met at a special session on Thursday, September 22, during ASHP Policy Week. Following a presentation and question-and-answer session conducted by [Dr. Mark Hughes](#), the Task Force discussed the policy and statement and recommended revising them. The Task Force agreed at the meeting that ASHP should maintain its stance of neutrality regarding pharmacist participation in assisted suicide as well as laws that permit it but recognized the

need to update the terminology of the position and the content of the statement. Following the Policy Week meeting, the Task Force considered several draft revisions to ASHP policy 9915 and recommended amending the policy as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To affirm that ~~the a pharmacist's decision to participate or decline to participate in the use of medications in assisted suicide~~ medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To ~~remain~~ take a stance of studied neutrality on the issue of health professional participation in assisted suicide of patients who are terminally ill ~~legislation that would permit medical aid in dying for competent, terminally ill patients~~; further,

~~To offer guidance to health system pharmacists who practice in states in which assisted suicide is legal.~~

One of the Task Force's first decisions was selecting a term to describe the practice. The Task Force chose *medical aid in dying* because it is more accurate, objective, and recognizable than other terms. The Task Force concluded that the term *physician-assisted suicide* is inaccurate for several reasons. First, laws that permit the practice frequently include a provision that explicitly excludes actions taken under the law from the legal definition of suicide, and those laws sometimes explicitly reject use of the terms *assisted suicide* or *physician-assisted suicide*. Second, as noted in the American Public Health Association Policy, [Patients' Rights to Self-Determination at the End of Life](#), the American Psychological Association has recognized that "the reasoning on which a terminally ill person (whose judgments are not impaired by mental disorders) bases a decision to end his or her life is fundamentally different from the reasoning a clinically depressed person uses to justify suicide," and numerous medical and legal experts agree that the term *suicide* "is inappropriate when discussing the choice of a mentally competent terminally ill patient to seek medications that he or she could consume to bring about a peaceful and dignified death." In addition, any term with the word *physician* in it minimizes the roles of other healthcare professionals in the practice, including pharmacists and hospice nurses, for example. The Task Force declined to use the term *death with dignity*, however commonly it is used in law and discourse, because the term is clearly not objective. As Dr. Hughes pointed out in his presentation, dignity has many aspects, and proponents on both sides of the debate argue that they are upholding the dignity of the individual. The Task Force considered numerous other terms (e.g., assisted death, hastened death) but decided against them because they have the same flaws as the others or are not commonly used.

In addition, the Task Force considered the use of studied neutrality by professional associations. The Task Force appreciated that the primary goal of studied neutrality is "to guide action that does not afford material advantage to a [particular] group." The Task Force acknowledged the diversity of views of ASHP members and other pharmacists and concluded

that a position of studied neutrality would promote patient autonomy and access to care and protect pharmacists' professional integrity and comity. The Task Force agreed that, as before, ASHP policy on the topic should focus primarily on the patient. The Task Force was concerned that a stance against pharmacist participation could interfere with a patient's right to access to obtain legally prescribed and medically indicated treatments (ASHP policy 0610, [Pharmacist's Right of Conscience and Patient's Right of Access to Therapy](#)). Further, the Task Force was concerned that a stance against pharmacist participation would infringe on the moral and ethical prerogatives of pharmacists and could introduce the possibility, however remote, that pharmacists could face legal or professional sanctions for participating in a legal practice. Similarly, the Task Force recognized that adopting a position in favor of participation would infringe on the moral and ethical prerogatives of pharmacists to decline to participate in therapies they consider morally, religiously, or ethically troubling.

The Task Force's recommendation of a position of studied neutrality on legislation allowing medical aid in dying was based on similar reasoning. A stance against such legislation could inhibit public discourse on an important healthcare topic and potentially limit patient access to desired therapies. In addition, a stance against such legislation could negatively affect public and professional perception of pharmacists who chose to participate. A stance in favor of such legislation would not serve the interests of ASHP members who oppose the practice and could negatively affect public and professional perception of pharmacists who decline to participate. Finally, a stance in favor of either side would alienate a significant number of pharmacists and damage the comity of the profession.

The Task Force also recognized that, given the widespread adoption of medical aid in dying, ASHP has an obligation to the pharmacists it serves and the patients they care for to continue to provide education about the topic but agreed that such education should encompass the broad spectrum of end-of-life care rather than focus solely on medical aid in dying. The Task Force noted that such education is the subject of ASHP policy 0307, [Support for Dying Patients](#), and concluded that any statement regarding education in this policy would be redundant. To help pharmacists navigate the issues presented by medical aid in dying, the Task Force recommended revising the [ASHP Statement on Pharmacist's Decision-making on Assisted Suicide](#) to provide an overview of the guiding principles for the pharmacist's decision-making on the topic, including professional tradition, respect for the patient, and professional obligations.

Genesis of ASHP Policy on Assisted Suicide

In September 1997, the ASHP Council on Legal and Public Affairs (now the Council on Public Policy) voted to develop a policy on the role of the pharmacist in assisted suicide. In March 1998, ASHP President John E. Murphy appointed a task force to develop an ASHP policy that would serve as ASHP's official stance on the concept of healthcare professionals assisting in the death of patients and offer practical guidance on the responsibilities, duties, and areas of concern that face practitioners in jurisdictions in which assisted suicide is legal. The task force included ASHP members (including a pain management practitioner) and three outside experts: a legal scholar, a former executive of a professional society with a sociological perspective, and an ethicist.

The Council and the Board concluded that ASHP's policy on the practice of assisted suicide at the public policy level and at the individual practitioner level should be neutral. The Council and the Board emphasized that the focus of ASHP policy should be on patients and caregivers, including family members, and highlighted existing ASHP policies regarding conscientious objection, use of drugs in capital punishment, adequate pain management, and appropriate care for dying patients.

ASHP Policies on Assisted Suicide and Related Issues

ASHP Policy on Assisted Suicide (9915)

To remain neutral on the issue of health professional participation in assisted suicide of patients who are terminally ill; further,

To affirm that the decision to participate in the use of medications in assisted suicide is one of individual conscience; further,

To offer guidance to health-system pharmacists who practice in states in which assisted suicide is legal.

Pharmacist's Right of Conscience and Patient's Right of Access to Therapy (0610)

To recognize the right of pharmacists, as health care providers, and other pharmacy employees to decline to participate in therapies they consider to be morally, religiously, or ethically troubling; further,

To support the proactive establishment of timely and convenient systems by pharmacists and their employers that protect the patient's right to obtain legally prescribed and medically indicated treatments while reasonably accommodating in a nonpunitive manner the right of conscience; further,

To support the principle that a pharmacist exercising the right of conscience must be respectful of, and serve the legitimate health care needs and desires of, the patient, and shall provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist's values, beliefs, or objections.

Pharmacist Role in Capital Punishment (1531)

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

To oppose pharmacist participation in capital punishment; further,

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

Pharmacist Support for Dying Patients (0307)

To support the position that care for dying patients is part of the continuum of care that pharmacists should provide to patients; further,

To support the position that pharmacists have a professional obligation to work in a collaborative and compassionate manner with patients, family members, caregivers, and other professionals to help fulfill the patient care needs, especially the quality-of-life needs, of dying patients of all ages; further,

To support research on the needs of dying patients; further,

To provide education to pharmacists on caring for dying patients, including education on clinical, managerial, professional, and legal issues; further,

To urge the inclusion of such topics in the curricula of colleges of pharmacy.

Pain Management (1106)

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

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

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To encourage the education of pharmacists, pharmacy students, and other health care providers regarding the principles of pain management and methods to minimize drug diversion.

Members of the Joint Council Task Force

Council on Pharmacy Management

Roger Woolf, *Chair* (Washington)
Tricia Meyer, *Vice Chair* (Texas)
Maxwell Anderegg, *Student* (Iowa)
Nitish Bangalore (Wisconsin)
Bradley Cagle, *New Practitioner* (Tennessee)
W. Lynn Ethridge (South Carolina)
Ken Jozefczyk (Georgia)
Christine Marchese (Rhode Island)
Katherine Miller (Kansas)
Robert Oakley (Kentucky)
Richard Pacitti (Pennsylvania)
Cynthia Williams (Virginia)
Tim Brown, *Board Liaison* (Ohio)

Council on Pharmacy Practice

Tate Trujillo, *Chair* (Indiana)
Lisa Mascardo, *Vice Chair* (Iowa)
Delaram Bahmandar, *New Practitioner*
(Missouri)
Noelle Chapman (Illinois)
Mark Dunnenberger (Illinois)
Donald Filibeck (Kansas)

Michael Ganio (Ohio)
Benjamin Groves, *Student* (Florida)
Jason Hutchens (Tennessee)
LeeAnn Miller (Connecticut)
Joseph Slechta (Kansas)
Elizabeth Wade (New Hampshire)
Jennifer Schultz, *Board Liaison* (Montana)

Council on Public Policy

Gloria Sachdev, *Chair* (Indiana)
Pamela Stamm, *Vice Chair* (Georgia)
Ewa Dzwierzynski (Rhode Island)
Tara Feller, *New Practitioner* (Maryland)
Christopher Fortier (Massachusetts)
Erin Fox (Utah)
Carla Frye (Nebraska)
Mark Hamm (Ohio)
Melissa Ortega (Massachusetts)
Michael Powell (Nebraska)
Maria Serpa (California)
Danielle Thanh, *Student* (California)
Ranee Runnebaum, *Board Liaison* (New Mexico)

House of Delegates

Board of Directors Report on Policy Recommendations from ASHP Councils

as of April 11, 2017

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COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATIONS

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

Todd A. Karpinski, *Board Liaison*

Council Members

Meghan D. Swarthout, *Chair* (Maryland)
Nicole Clark, *Vice Chair* (Massachusetts)
Sophia Chhay, *New Practitioner* (Maryland)
Seena Haines (Mississippi)
Thaddaus Hellwig (South Dakota)
Patricia Knowles (Georgia)
Dena Lehmann, *Student* (Pennsylvania)
Neil MacKinnon (Ohio)
Krystal Moorman (Utah)
Kristine Parbuoni (California)
Mark Sinnett (New York)
Lanita S. White (Arkansas)
Erika Thomas, *Secretary* (Maryland)

1. Workforce Diversity

- 1 To affirm that a diverse and inclusive workforce contributes to health equity and
- 2 health outcomes; further,

- 3 To advocate for the development of a workforce whose background, perspectives,
- 4 and experiences reflect the diverse patients for whom pharmacists provide care.

Rationale

As the U.S. becomes more heterogeneous, the pharmacy workforce should reflect and respond to this increasingly diverse patient base. An inclusive pharmacy workforce is best able to positively impact the health and wellness of patients for whom pharmacists provide care. According to the Institute of Medicine, increasing diversity among healthcare providers is associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better educational experiences for health professions students.^{1,2} Diversity in the pharmacy workforce includes, but is not limited to, the categories of sexual orientation and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion, and persons with disabilities.³ A diverse pharmacy workforce will provide the best care for all patients.

¹ Smedley BD, Butler AS, Bristow LR, eds. In the nation's compelling interest: ensuring diversity in the health-care workforce. Washington, DC: National Academies Press; 2004.

² Cohen JJ, Gabriel, BA, Terrell C. The case for diversity in the health care workforce. *Health Aff.* 2002;21(5):90-102.

³ American Medical Association. AMA policies on LGBT issues. <http://www.ama-assn.org/ama/pub/about->

Background

A 2015 House of Delegates recommendation urged the Council to consider a policy to promote, support, and advocate for developing a diverse workforce and addressing gaps in healthcare including, but not limited to, race and ethnicity as well as other gaps, such as socioeconomic and literacy gaps. The 2015 Council reviewed related ASHP policies 1414 and 0510 and decided to recommend amending policy 1414. The Council felt it important to note that the [ASHP Statement on Racial and Ethnic Disparities in Health Care](#) complements the ASHP policy positions, so all three must be considered when determining whether new or revised policy is needed. The 2016 House of Delegates voted to strike the final clause of policy 1414, “To advocate for an ethnically and culturally diverse workforce,” with an accompanying recommendation that the Council on Education and Workforce Development craft a separate policy on cultural and ethnic diversity of the workforce. The ASHP Board concurred with this decision. Additionally, there was a recommendation at the 2016 House of Delegates to expand the statement to be more inclusive by including sexual orientation and gender expression in the policy to better reflect workforce and patient-care needs.

2. ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process

- 1 To encourage all educators of the pharmacy workforce to use ASHP statements,
- 2 guidelines, and professional policies as an integral part of education and training.

(Note: This policy would supersede ASHP policy 0705.)

Rationale

ASHP members create professional policy that reflect best practices and influence the future direction of the profession and patient care. ASHP's professional policies contain varying levels of detail, but all contain guiding principles for the profession. The use of professional policy should be incorporated into all forms of professional education, including pharmacy and technician students, residents, and practitioners and widely used across the pharmacy profession.

Background

The Council voted to recommend amending ASHP policy 0705, ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To encourage all educators ~~faculties in colleges of pharmacy~~ of the pharmacy workforce ~~and preceptors of ASHP-accredited residency training programs~~ to use ASHP statements, guidelines, and professional policies as an integral part of education and training programs and courses.

ama/our-people/member-groups-sections/glb-t-advisory-committee/ama-policy-regarding-sexual-orientation.page
(accessed 2016 Oct 4).

The Council agreed that the use of ASHP statements, guidelines, and professional policies should not be limited to pharmacy college faculty alone, and that all ASHP guidance documents should be used widely across the entire pharmacy profession, including, but not limited to, residency training programs and pharmacy technician training and education programs.

3. Educational Program Resources for Affiliated State Societies

To discontinue ASHP policy 0215, which reads:

- 1 To assist ASHP-affiliated state societies with information about potential educational
- 2 program resources.

Background

The Council agreed that this process has been incorporated into routine ASHP practice and is no longer needed as a policy position. ASHP provides an array of large and small-scale educational programming for affiliates, including: the provision of Board and staff speakers on topics of national, professional and member interest; monthly live and recorded webinars on topics of professional interest; sessions on critical topics at both the Summer and Midyear Clinical Meetings; monthly newlinks; links on dedicated Connect pages for affiliates and other programming as suggested by state affiliates. Additionally, ASHP continues to work with a variety of programming providers to continue to evaluate and potentially add educational program resources for use by state affiliates, including actual live and recorded programming, platforms for use in recording and storing programming and identifying/evaluating potential program partners.

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.)

- Career Counseling (8507)
- Requirement for Residency (0701)
- Residency Programs (0704)
- Preceptor Skills and Abilities (1201)
- Qualifications and Competencies Required to Prescribe Medications (1202)
- Qualifications of Pharmacy Technicians in Advanced Roles (1203)

Other Council Activity

House of Delegates New Business Item: Impact of Intern Hours Changes Required For Licensure

Council members discussed the new business item that was presented to the 2016 House of Delegates related to recent California Board of Pharmacy action that eliminated the requirement for non-academic internship hours to permit out-of-state applicants to take the California State Licensure Examination. The Council addressed the question of whether internship hours acquired outside of introductory and advanced pharmacy practice experiences (IPPE/APPE) rotations are necessary and how much they contribute to new practitioner readiness. Council members felt that current ASHP policy 1110, Pharmacy Internships, is relevant and appropriate.

2014 Workforce Survey

The [2014 National Pharmacist Workforce Survey](#) provides an update on the pharmacy workforce and compares results to the last survey in 2009. The primary purpose of the survey is to collect reliable information on demographic characteristics, work contributions, and quality of work-life of the pharmacist workforce in the United States. Results of the survey allow analyses and trends in pharmacy workforce issues. The survey is conducted on an approximately four- to five-year cycle. The Council reviewed the most recent survey and noted the following developments:

- The proportion of women in the workforce continues to increase.
- Job satisfaction and career commitment is high.
- Pharmacists with a Doctor of Pharmacy degree rose significantly since 2009.
- Increasing job stress may be contributing to decreased job satisfaction.

- Those most satisfied with their job work outside of direct patient care.
- Pharmacists in chain settings work the longest hours.
- Time spent in patient-care services not associated with medications has increased since 2009.

Overall, the Council felt the workforce report included positive information for the profession. The Council recommended that ASHP support strategies to reduce workplace-related stress such as developing web-based or other educational resources, supporting ongoing research, and showcasing proven stress-reducing models.

Final Report on Pharmacy Technician Workforce Survey

The Council discussed results of the 2015 [Pharmacy Technician Workforce Survey](#). Council members noted that roles for pharmacy technicians are emerging in automation, inventory, procurement, patient safety, and quality assurance. The Council noted that the survey indicated that pharmacy technician survey participants reported feeling threatened by technology, undervalued in the workplace, and inadequately trained. It was also noted that survey participants were highly satisfied with pharmacist co-workers and rated job satisfaction highly. The Council agreed that ASHP should continue to develop more resources for technicians and technician education. The Council was advised that a consensus conference of pharmacy technician stakeholders will be held in February 2017. One objective of this conference is to develop consensus in the area of defining the entry-level (“generalist”) pharmacy technician. The Council also recommended that ASHP explore opportunities to conduct a pharmacy technician workforce survey specifically for technicians who work in health systems.

Technician Workforce: Meeting 2020 Goal

The Council discussion focused on updates and new educational opportunities that will assist in meeting the Pharmacy Technician Certification Board (PTCB) goal of requiring that initial candidates for certification complete a pharmacy technician education program accredited by the American Society of Health-System Pharmacists and the Accreditation Council for Pharmacy Education by the year 2020. The purpose of this goal is to advance pharmacy technician qualifications by elevating PTCB’s standards for national certification and recertification. The Council received an overview of the status of PTCB 2020 Initiative and discussed new educational models such as the newly accredited distance-learning program. The Council urged ASHP to continue to share information with members on advanced technician roles. The Council also encouraged continued communication with ASHP state affiliates on how to work with boards of pharmacy to require technician certification. Finally, Council members encouraged support for PTCB to expand specialty certification for advanced roles.

Residency Program Accreditation: Meeting 2020 Goal

The Council discussed progress on the ASHP goal that by 2020 completion of an ASHP-accredited postgraduate year one (PGY1) residency should be required for entry into practice for pharmacists who will be providing direct patient care. Council members agreed that

significant progress has been made in closing the gap between the number of available residency programs and the number of pharmacy graduates seeking residencies. The Council was also updated on advocating for reinstatement of CMS funding for PGY2 residencies.

The Council determined that existing ASHP policies are appropriate, robust, and supportive of the residency program accreditation goal. The Council encouraged ASHP to develop and market materials that support hospitals wishing to develop residency programs that do not have a teaching mission, including information on how to justify resident position to the C-suite. Finally, ASHP was encouraged to provide education on layered learning practice models.

Provider Status Readiness

The Council discussed readiness of the profession and ASHP members for passage of H.R. 592/S. 314, the Pharmacy and Medically Underserved Areas Enhancement Act (the Act). Member readiness needs for becoming providers in the Social Security Act were addressed. The Council recognized ASHP for providing robust education on advocating for provider status. Council members felt that pharmacy departments would be viewed differently by the C-suite after passage of this legislation—no longer as an expense, but as a provider. The need to educate the C-suite on new roles for pharmacists was discussed.

The Council felt that current ASHP policy adequately address policy needs for provider status readiness. The Council suggested developing educational resources for ASHP members, including educational tools on coding and billing as well as practical skills development education on providing direct patient care. The Council agreed that developing readiness packages for ASHP state affiliates to work with state boards of pharmacy executives to lead practice act and scope of practice changes would be valuable. The need to collect baseline data on current pharmacist-provided patient-care activities to assess the impact of provider status in underserved communities was discussed, and the Council recommended that ASHP work with other members of the [Patient Access to Pharmacists' Care Coalition](#) to explore this type of data collection. The Council also suggested that college of pharmacy faculty and pharmacy students will also need to be educated on new patient-care responsibilities and techniques as well as billing and coding.

Intercouncil Task Force on ASHP Policy on Formulary and Pharmacy and Therapeutics Management

The Council was informed that the goal of this Task Force is to assure consistency between all formulary and pharmacy and therapeutics management policies and assure that these policies are updated.

Student Debt

Tuition at colleges of pharmacy continues to rise, as does the debt of students graduating with Doctor of Pharmacy degrees. The majority of students, 87.7%, have borrowed money to finance education, while only 12.5% did not. The American Association of Colleges of Pharmacy

(AACCP) conducts an annual survey of graduating students. According to the 2016 National Summary Report, the average amount borrowed to finance pharmacy education for both public and private institutions was \$150,000, down from \$157,425 in 2015.

The Council noted several concerns about rising level of pharmacy student debt including that debt repayment may deter those interested in pursuing residencies and reduce the pool of potential pharmacy students.

The Council concluded that ASHP policy on the topic was not warranted at this time but offered suggestions for action on the topic. Council members identified many online resources available to students and suggested collecting them into a resource. Residents could be directed to this resource by residency program directors.

Update on 2017 Technician Consensus Conference

The Council received an update on the proceedings of the 2017 Pharmacy Technician Stakeholder Consensus Conference which focused on developing consensus across the profession on the knowledge, skills, and abilities required for entry-level pharmacy technicians. Conference participants generally agreed on the need for accredited training and certification. Conferees also agreed on a set of recommendations and plan to meet in the future to discuss how to implement these recommendations. Conference proceedings will be shared at a future meeting of the Council. The Council will examine ASHP policy at that time.

COUNCIL ON PHARMACY MANAGEMENT

POLICY RECOMMENDATIONS

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

Timothy R. Brown, *Board Liaison*

Council Members

Roger A. Woolf, *Chair*
Tricia Meyer, *Vice Chair* (Texas)
Maxwell Anderegg, *Student* (Iowa)
Nitish Bangalore (Wisconsin)
Bradley Cagle, *New Practitioner* (Tennessee)
W. Lynn Ethridge (South Carolina)
Kenneth Jozefczyk (Georgia)
Christine Marchese (Rhode Island)
Katherine Miller (Illinois)
Robert S. Oakley (Kentucky)
Richard Pacitti (Pennsylvania)
Cynthia Williams (Virginia)
David Chen, *Secretary* (Maryland)

1. Any Willing Provider Status for Pharmacists and Pharmacies

- 1 To advocate for federal and state legislation and regulations that will grant any
- 2 willing provider status to pharmacists and pharmacies and improve patient care
- 3 access and continuity of care; further,
- 4 To support affiliated state societies in advocating that pharmacists and pharmacies
- 5 be included in state any willing provider legislation or regulation.

Rationale

Historically, any willing provider statutes have primarily been a concern for pharmacists in the traditional retail or community pharmacy practice settings, but as hospitals and healthcare organizations have become more engaged in developing ambulatory care service lines, pharmacists working in those settings increasingly find themselves excluded from payer networks. As pharmacists obtain provider status in a number of states, they recognize the infrastructure required to implement direct, independent patient care and billing for provider-based services. Including pharmacists and pharmacies as providers in any willing provider statutes will improve patient access to pharmacists' care by allowing pharmacists to access payer networks, assuming those pharmacists can fulfill the terms and conditions required by payers.

Background

The [National Conference of State Legislatures](#) (NCSL) describes any willing provider (AWP) statutes, sometimes referred to as any authorized provider statutes, as follows:

Any willing provider statutes are laws that require health insurance carriers to allow healthcare providers to become members of the carriers' networks of providers if certain conditions are met. Such statutes prohibit insurance carriers from limiting membership within their provider networks based upon geography or other characteristics, so long as a provider is willing and able to meet the conditions of network membership set by the carrier.

AWP laws can be broad in scope, applying to all or most licensed providers in the state. Broad laws typically either spell out a list of providers covered by the provisions (e.g., physicians, pharmacists, chiropractors, speech therapists, podiatrists, optometrists, facilities, etc.) or assert that the provisions apply to all providers licensed in the state without specifically listing any.

AWP laws can also be limited in scope. Frequently, the limited provisions apply to only pharmacies or pharmacists. In some cases, they apply to a limited number of allied professionals such as chiropractors, optometrists, psychologists, and social workers.

According to the NCSL, in late 2014 there were 27 states with AWP statutes. Although many of these laws have been in force for decades, the most recently enacted changes in AWP laws were passed in 2013, and in November 2014 South Dakota voters approved a broad AWP binding ballot question.

The Council reviewed ASHP policy on the impact of insurance design and manufacturers' decisions on patients' ability to obtain access to medications and pharmacy services. During this review the Council concluded it was necessary to review the impact of AWP laws and regulations on pharmacists' ability to care for patients and to offer provider-based services, both in the states where pharmacists have achieved provider status and in those where they have not. The Council discussed the three components that can be required to support access to patients and payers: a strong state scope of practice and/or collaborative practice act, a payer that recognizes pharmacists as providers, and the opportunity to meet payers' requirements to provide patient care services (i.e., AWP statutes).

2. Pharmaceutical Distribution Systems

- 1 To support drug distribution business models that meet the requirements of
- 2 hospitals and health systems with respect to availability and timely delivery of
- 3 products, minimizing short-term outages and long-term product shortages,
- 4 managing and responding to product recalls, fostering product-handling and
- 5 transaction efficiency, preserving the integrity of products as they move through the
- 6 supply chain, and maintaining affordable service costs; further,

- 7 To advocate that distributors not be permitted to make availability of drug products
- 8 contingent on how those drugs products are used.

(Note: This policy would supersede ASHP policy 1016.)

Rationale

Wholesaler and distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. Recently, some wholesalers have required that pharmacies ensure certain drugs are not used or sold for use for particular purposes, and there are concerns that this practice could grow. ASHP supports wholesaler and distribution business models that meet the requirements of hospitals and health systems, which includes the ability for pharmacies to obtain drug products for established patient care uses without restriction.

Background

The Council voted to recommend amending policy 1016, Pharmaceutical Distribution Systems, as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To support ~~wholesaler/~~drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To advocate that distributors not be permitted to make availability of drug products contingent on how those drugs products are used.

The Council discussed the 2016 ASHP House of Delegates recommendation describing the need for ASHP to consider the impact of mandated requirements by wholesalers for the purchasing pharmacy “to sign an agreement that they would not purchase for or resell certain agents to prisons because several pharmaceutical manufacturers were mandating this. If the agreement was not signed, the pharmacy would not be allowed to purchase these agents for their patients.” The concern was this requirement could set a dangerous precedent, with major implications on patient care for healthcare systems that do not agree with pharmaceutical company’s positions. This requirement is currently related to the European Commission’s [imposition of restrictions](#) on the export of anesthetics used in U.S. executions, which has the potential to exacerbate the already extreme drug shortages in the 34 states with the death penalty. In addition, the European Commission has added eight barbiturates to its list of restricted products on the grounds that they may be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment. Among the eight are

pentobarbital and sodium thiopental, the two drugs on which almost all U.S. executions depend.

The Council took into consideration ASHP's existing policy on capital punishment, recognizing the relationship between the 2016 ASHP House of Delegates recommendation and the ASHP policy. From this discussion the Council concluded there could be circumstances in which wholesalers or other drug distribution businesses might seek to restrict the use of drugs for established, evidenced-based patient care uses, which is not in the best interests of patients.

3. Mobile Health Tools, Clinical Apps, and Associated Devices

- 1 To advocate that patients, physicians, pharmacists, and other healthcare
- 2 professionals be involved in the selection, approval, and management of mobile
- 3 health tools, clinical software applications ("clinical apps"), and associated devices
- 4 used by clinicians and patients for patient care; further,

- 5 To advocate that decisions regarding the selection, approval, and management of
- 6 mobile health tools, clinical apps, and associated devices should further the goal of
- 7 delivering safe and effective patient care and optimizing outcomes; further,

- 8 To advocate that mobile health tools, clinical apps, and associated devices that
- 9 contain health information be interoperable and, if applicable, be structured to allow
- 10 incorporation of health information into the patient's electronic health record and
- 11 other essential clinical systems to facilitate optimal health outcomes; further,

- 12 To advocate that pharmacists be included in regulatory evaluation and approval of
- 13 mobile health tools, clinical apps, and associated devices that involve medications or
- 14 medication management; further,

- 15 To foster development of tools and resources to assist pharmacists in designing and
- 16 assessing processes to ensure safe, accurate, supported, and secure use of mobile
- 17 health tools, clinical apps, and associated devices.

Rationale

The use of mobile devices (e.g., smartphones, tablets) has become commonplace. Over 68% of adults own a smartphone, and 62% of those use their smartphones to access health information. In addition to these mobile devices, use of remote monitoring devices is also being rapidly integrated into healthcare. According to a 2015 survey, although only 16% of healthcare professionals currently use mobile health tools in caring for patients, 46% plan to do so in the next five years. With the proliferation of mobile health tools, clinical apps, and associated devices, healthcare organizations need to address the potential risks of application use. Particular concerns include (1) assessing the quality of mobile health tools, clinical apps, and

associated devices; (2) standardizing choices and use across the organization; and (3) ensuring the security of data and data storage.

To maximize the effectiveness of mobile health tools, clinical apps, and associated devices, they must be selected, approved, and managed with the goal of improving care and with input from representatives of all affected parties, including patients, physicians, pharmacists, and other healthcare professionals. In addition, their effectiveness is enhanced when they are interoperable (as described in ASHP policy 1302, Interoperability of Patient-Care Technologies) and the data stored within them can be incorporated into the patient's electronic health record and other essential clinical systems.

Providers and patients currently have little guidance regarding use of these resources or the management of the data they provide. The Food and Drug Administration and other regulatory agencies are just beginning to determine the scope of their oversight. As medication-use experts, pharmacists can contribute to the regulatory evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management. In addition, ASHP is committed to fostering development of resources to help pharmacists ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices.

Background

The Council discussed the growing development and use of mobile health tools, clinical apps, and associated devices. Many of these tools are specifically targeted to assisting individuals in their own health and wellness management. Patient engagement with these devices and apps can provide benefits such as greater adherence, reduced recall (memory) burden, and less manual entry of health information. The Food and Drug Administration (FDA) defines a "mobile medical app" as a software application that can be executed on a mobile platform (i.e., a handheld, commercial, off-the-shelf computing platform, with or without wireless connectivity) or a web-based software application that is tailored to a mobile platform but is executed on a server and meets the definition of device in section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), and is intended to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device.

The Council discussed cases and experiences with hospitals and health systems adopting use of mobile apps. One of the case studies discussed was Ochsner, which was the first hospital to integrate the Apple HealthKit with their Epic system, starting in 2014. Ochsner closely tracks, monitors, and reports on the very positive patient outcomes of their Integrated & Connected Health programs. Ochsner's OBar is a retail store that offers digital tablets loaded with vetted mobile apps to support consumer health and sells discounted devices (e.g., activity trackers, wireless scales, blood pressure cuffs, and glucometers). Other health systems, such as Carolinas HealthCare System, feature a combination of homegrown and commercial apps on its website for patients to access medical-related information. The UK's National Health Service announced that 20 mobile health (mHealth) apps and devices will be offered free of charge to patients and providers to boost innovation and patient engagement; this service is slated to begin in 2017.

The Council discussed potential issues with medical apps, including the similarity of those risks to those of traditional medical devices, and noted that certain mobile medical apps can pose potential risks to public health. The FDA intends to apply its regulatory oversight to

only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. The FDA believes that this subset of mobile medical apps poses the same or similar potential risks to the public health as currently regulated medical devices if they fail to function as intended. A combined 84 percent of mobile app users and mobile app executives believe that their mobile health apps are adequately secure, and 63% believe that app providers are doing everything they can to protect their mobile health apps. An astounding 98% of mobile apps tested lacked binary protection, and most consumers state they would change providers if they were aware of how insecure the mobile apps are. Additionally, the Council noted the large and growing number of apps that will not be covered by FDA oversight of medical devices and emphasized the importance of having pharmacists assume an important role in the selection and management of medication-related apps that may be suggested for patients' use or that patients may use on their own.

The ASHP Section of Pharmacy Informatics and Technology Executive Committee representative to Policy Week provided perspectives for the Council, mentioning the Section's interest in pursuing the development of education, resources, and a statement or publication for healthcare organizations to use when making decisions about the use of apps in patient care. In addition, the Section Executive Committee reviewed and endorsed the policy recommendation.

4. Controlled Substance Diversion Prevention

- 1 To encourage healthcare organizations to develop policies that delineate the roles,
- 2 responsibilities, and oversight of all personnel who handle controlled substances to
- 3 ensure compliance with applicable laws and scopes of practice; further,

- 4 To encourage healthcare organizations to ensure that all healthcare workers are
- 5 appropriately screened for substance abuse prior to initial employment and
- 6 monitored on a continuous basis to support a safe patient-care environment, protect
- 7 co-workers, and discourage controlled substances diversion.

Rationale

Abuse of controlled prescription drugs (CPDs) is on the rise in the U.S. According to the [2014 National Drug Threat Assessment Summary](#) from the Drug Enforcement Administration (DEA), deaths involving CPDs outnumber those involving heroin and cocaine combined. Additionally, the economic cost of nonmedical use of prescription opioids alone in the U.S. totals more than \$53 billion annually. All pharmacies and healthcare institutions that handle controlled substances are required to have storage and distribution systems in place to prevent diversion. Due to the numerous medication access points in most hospital distribution systems, diversion is sometimes difficult to detect. Theft of controlled substances by healthcare workers remains a serious problem that can lead to patient harm and jeopardize patient safety. Drug addiction among healthcare workers is well documented. [One survey](#) suggested that nurses who reported a perception of easier availability of controlled substances were almost twice as likely as others to divert and use a controlled substance. In [another survey](#) published in *AJHP*, 19% of

pharmacists reported use of a controlled substance without a prescription during the preceding 12 months. Even the most conservative estimates are that 8–12% of physicians will develop a substance abuse problem at some point during their career, although the exact rate of substance abuse among physicians is uncertain.

Pharmacy managers and pharmacists-in-charge have increasing responsibility for ensuring controlled substance management and storage across large healthcare organizations. This expanded responsibility has increased the risk to organizations as acquisitions of physician office practices, clinics, and other non-hospital-based business units continue. To ensure compliance with applicable laws and scopes of practice, ASHP advocates that healthcare organizations develop policies to describe the roles, responsibilities, and oversight of all personnel handling controlled substances throughout the organization. ASHP supports pre-employment screening and continuous monitoring of all healthcare workers to reduce the risk of controlled substances diversion.

Background

The Council considered this topic in response to a recommendation from the House of Delegates as well as staff recommendation. In 2015, the Council proposed new policy addressing controlled substance management and initiated work on guidelines to support improved controlled substance diversion prevention programs. During the development of the guidelines there continued to be a large number of publicized cases of controlled substance diversion in the U.S. These cases, along with gaps identified during the development of the guidelines, demonstrated the need for ASHP policy regarding organizational policy for managing employees who handle controlled substances.

5. 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 verification of reimbursement, billing, finance, and prior
- 4 authorization, for the healthcare 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 1205.)

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 healthcare 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 to recommend amending ASHP policy 1205, Revenue Cycle Compliance and Management, as follows (underscore indicates new text):

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

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

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

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

The Council discussed ASHP policies related to finance and management of the revenue cycle. The Council concluded that ASHP policies covered most critical elements but agreed that, given the increasing number of payer designs that do not include hospitals in network and the growing requirements for prior authorizations, it is important to include the need to verify reimbursement for medication therapies in managing the complete revenue cycle.

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.)

- Staffing for Safe and Effective Patient Care (0201)
- Performance Improvement (0202)
- Reimbursement for Unlabeled Uses of FDA-Approved Drug Products (0206)
- Standard Drug Administration Schedules (0707)
- Financial Management Skills (1207)
- Transitions of Care (1208)
- Value-Based Purchasing (1209)
- Pharmacist's Role in Health Care Information Systems (1211)

Other Council Activity

Formulary Management for Health Systems and Challenges Due to External Payers and Escalating Drug Prices

The Council voted to explore convening an interprofessional task force to assess the Principles of a Sound Drug Formulary System to ensure the principles described are current, based on the current healthcare environment.

The environment of formulary management impacting health-system pharmacy leaders has changed dramatically, which includes the influence of external payers, increasing drug prices, and the challenges of establishing formulary and drug policy decisions across multi-hospital systems and integrated delivery networks.

The "Principles of a Sound Drug Formulary System" was developed in collaboration with an interprofessional group of healthcare associations. The original document was approved in 2000 and affirmed in 2011. Over the past 30 years the maturation of prescription benefit management services, the introduction of Medicare Part D, changes in how group purchasing and industry contracting are handled, and the increasing costs of medications have resulted in the development of many formulary management systems across different sectors of healthcare and unique formularies among these sectors and associated payers. Additionally, even within health systems, as the accountability of patients across the continuum of care increases and selecting the most efficacious and economical medications (which may not be the best economic outcome for all practice sites of the health system) has begun to result in a new paradigm for formulary management decisions.

Controlled Substance Diversion and Patient Access

The Council voted to recommend that the Council on Public Policy amend ASHP policy 9103, Drug Testing, to read as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To recognize the use of pre-employment drug testing, random drug testing, or drug testing for cause during employment based on defined criteria and with appropriate validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that appropriate drug testing panels are utilized that have demonstrated effectiveness verifying presence of substances commonly abused and/or used illegally; further,

To advocate that in the event a healthcare worker tests positive to drug testing, then organization attempts to provide follow-up with infectious disease testing.

Controlled substance diversion and abuse has reached the attention at the highest levels in the U.S., with even the White House weighing in on the crisis. In the past 4-5 years, the DEA has levied large fines on chain drugstores, drug wholesalers, and, most recently, major hospitals. Pharmacy managers and pharmacists-in-charge have increasing responsibility of ensuring controlled substance management and storage across large healthcare organizations. The Council discussed the increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and the many challenges that exist for healthcare institutions in managing controlled substances.

The Council also discussed the recently completed [ASHP Guidelines on Preventing Diversion of Controlled Substances](#). During its development authors noted there was ASHP policy on what organizations should consider for pre-employment and for-cause drug testing but not for random drug testing, which is being considered by many healthcare organizations. To be in alignment with the recommendations of best practices in the newly developed guidelines the Council has recommended the proposed amendment.

The Council on Public Policy considered these suggestions and recommended amending policy 9103.

Formulary Management for Health Systems and ASHP Evaluation of Related Policies, Statements, and Guidelines

The Council voted to convene an intercouncil work group to conduct a thorough review of ASHP policies, statements, and guidelines related to pharmacy and therapeutics committees, formulary management, and drug policy development, with the purpose of ensuring ASHP

policies, statements, and guidelines reflect the current market environment and needs of ASHP members.

The Council discussed challenges facing health-system leaders, including:

- Pharmacy benefit managers dictating hospital formulary decisions (e.g., a hospital may have Brand A on the formulary, but a plan will not pay the provider unless they provide Brand B for both inpatient and outpatient prescriptions).
- Increasing pressure on pharmacy to hold the line on drug costs, which is quite challenging with the huge increases seen in the costs of brand and generic drugs, combined with the growth of the specialty drug market.
- Healthcare executives who may want simple solutions with unreasonable means for patient care, such as in one anecdote of a senior leader who was convinced that the path to cost savings was reducing the number of line items in the formulary, not looking at the utilization of the top 200 drugs that account for 80% of our total drug spend.
- Questions of ethics and patient access to expensive medications, drugs in short supply, and organizational budget discipline.
- Outpatient pharmacy charges and revenue optimization in a population health model.
- Specialty pharmacy and the impact of site-of-care decisions on which drugs are covered for patients.
- The challenge of determining whether certain chronic disease management drugs need to be or should be given during an inpatient admission.
- The impact on formulary decisions and cost management when drugs historically given in clinics may be administered in hospital, since the organization owns all the expense anyway and the inpatient setting may be felt to be best site of care.
- The need to reassess to role of pharmacy and therapeutics committees and the traditional membership of these committees.
- The impact of perpetual drug shortages on formulary management and patient safety.

The Council agreed that numerous challenges and environmental changes are making it increasingly difficult to manage budgets; the difficulty of ensuring hospital leadership understands the complexity of formulary management, the impact of payers, and the responsibility to patients require ASHP to assess its existing policies and resources for pharmacy leaders. The Council recommended that the key goals of an intercouncil workgroup would include a primary goal of establishing a sustainable formulary process to meet the needs of patients served across the continuum of healthcare organizations. Fundamental components would include:

- Effective data management that optimizes evidence, utilization, and cost.
- New pharmacy and therapeutics models that evaluate the need for new stakeholders, transitions of care, reimbursement, and maximum value for the community.
- Impact of rising drug costs and patient access, which should address the impact of drug shortages, rapid inflation, and predicted high drug costs, including the growing impact of limited drug distribution and payer-directed mandates affecting patient drug-use options.

The Council recommends this process because there are over 40 policy positions, statements, and guidelines developed by all councils.

Joint Council Task Force on ASHP Position on Assisted Suicide

The Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy met as a Joint Task Force to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following a presentation and question-and-answer session, the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors.

Value-based Drug Pricing

Council members identified the need for a definition of value-based drug pricing and suggested that more education of ASHP members and other pharmacy managers is necessary. Council members considered how value-based drug pricing is incorporated in current formulary processes. The challenges identified include the lack of integration between inpatient and outpatient formularies and the lack of information about the costs and benefits of particular medications. The Council considered how organizations will address evaluation of drugs approved by the FDA through an accelerated process that provides less data. The Council also discussed the difference between reimbursement models for inpatient and outpatient settings and how value-based drug pricing would differ between those two settings.

The Council suggested educating ASHP members through an *AJHP* editorial or primer. It was suggested that this would be a good topic for a *CPO Perspectives* column. The Council suggested that ASHP policy 1506, Premarketing Comparative Clinical Studies, and policy 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, advocate for the kinds of studies that could provide a basis for value-based drug pricing but do not address the topic of value-based drug pricing directly. The Council reviewed policy 1209, Value-Based Purchasing, and agreed the policy addresses the payer models designed for payment for patient care versus the actual pricing models for the purchase price of drugs. The Council agreed that further research could be done by reaching out to FIP members who practice in countries that have more experience with value-based drug pricing.

COUNCIL ON PHARMACY PRACTICE

POLICY RECOMMENDATIONS

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

Jennifer M. Schultz, *Board Liaison*

Council Members

Tate Trujillo, *Chair* (Indiana)
Lisa Mascardo, *Vice Chair* (Iowa)
Delaram Bahmandar, *New Practitioner* (Missouri)
Noelle Chapman (Illinois)
Mark Dunnenberger (Illinois)
Don Filibeck (Ohio)
Michael Ganio (Ohio)
Benjamin Groves, *Student* (Florida)
Jason Hutchens (Tennessee)
Joe Slechta (Kansas)
LeeAnn Miller (Connecticut)
Elizabeth Wade (New Hampshire)
Deborah Pasko, *Secretary*

1. Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use

- 1 To advocate that pharmaceutical manufacturers provide hazardous drug products
- 2 intended for home use in ready-to-administer packaging; further,
- 3 To advocate that, when hazardous drug products intended for home use are not
- 4 available from manufacturers in ready-to-administer packaging, pharmacists
- 5 repackage those drug products to minimize the risk of exposure; further,
- 6 To advocate that pharmacists provide education to patients and caregivers regarding
- 7 safe handling of hazardous drug products intended for home use.

Rationale

Home use of oral chemotherapy increases patient convenience and lowers healthcare costs, but it presents [unique safety risks](#). In a hospital or clinic setting, healthcare professionals manage the risks posed by hazardous drugs, defined as any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity ([NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings](#)). In the home environment, however, patients and caregivers must be prepared to fill that role. Ready-to-administer packaging of hazardous drugs minimizes patient, caregiver, and family exposure to hazardous drugs, promotes patient adherence, and enhances safe medication use. Ready-to-administer is defined as the product requires no manipulation before that patient

and/or caregiver can administer the medication. Versus ready-to-use packaging still may require a small amount of manipulation such as reconstitution, etc. These definitions are consistent with USP and ISMP per verbal communication. ASHP advocates that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging, and that when such packaging is not provided, pharmacists repackage those drug products to minimize exposure risk. ASHP further advocates that patients and caregivers be provided education regarding safe handling of hazardous drug products from a qualified healthcare professional, preferably a pharmacist experienced in managing the risks of hazardous drug products.

Background

The Council considered this topic in response to member suggestions and concerns expressed by the Institute for Safe Medication Practices (ISMP). The United States Pharmacopoeia (USP) has proposed a new General Chapter 800, Hazardous Drugs—Handling in Healthcare Settings, to provide standards to protect healthcare personnel who handle hazardous drugs. Chapter 800, however, does not address protection of patients, caregivers, and family members when hazardous drugs are used outside of healthcare facilities.

The Council wanted to develop policy that would encourage manufacturers to provide hazardous drugs in the most appropriate package and size conducive to patient needs to minimize exposure risk to patients, caregivers, and family members. The Council's concerns related to package type, quantities, and the safety of the container. Many chemotherapy regimens and prescriptions have predetermined quantities that are needed for the patient's protocol or regimen needs. The Council urged that packaging from manufacturers be ready to use and require as little manipulation as possible after dispensing to ensure safety and ease of use.

The Council reviewed ASHP policy position 402, Ready-To-Use Packaging for All Settings, and noted that the policy does not use the term *ready-to-administer* but rather *unit-of-use*. In the policy a "unit-of-use package" is defined as "a container--closure system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling." The Council was concerned that unit-of-use packaging may not necessarily be ready-to-administer and suggested re-titling the policy.

2. Expiration Dating of Pharmaceutical Products

- 1 To support and actively promote the maximal extension of expiration dates of
- 2 commercially available pharmaceutical products as a means of increasing access to
- 3 drugs and reducing healthcare costs; further,

- 4 To advocate that the Food and Drug Administration implement procedures to allow
- 5 pharmaceutical manufacturers to readily update expiration dates to reflect current
- 6 evidence; further,

- 7 To advocate that regulators and accreditation agencies recognize authoritative data
- 8 on extended expiration dates for commercially available pharmaceutical products.

(Note: This policy would supersede ASHP policy 9309.)

Rationale

Extending the expiration date of commercially available pharmaceutical products reduces healthcare costs and increases access. ASHP encourages pre- and post-marketing research on expiration dates and the use of the most current authoritative data on expiration dates in drug product management. The current process for updating expiration dates in drug product labeling presents barriers to timely revision, however, and should be streamlined to allow for timely updates. Until such a process is implemented, regulators and accreditation agencies should permit healthcare organizations to rely on authoritative data when determining appropriate extended expiration dates for commercially available pharmaceutical products.

Background

The Council reviewed ASHP policy 9309, Expiration Dating of Pharmaceutical Products, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs ~~and to recommend that pharmaceutical manufacturers review their procedures to accomplish this end;~~ further,

To advocate that the Food and Drug Administration implement procedures to allow pharmaceutical manufacturers to readily update expiration dates to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

The Council wanted to update the policy to achieve three goals: 1) clarify that the subject of the policy is commercially available pharmaceutical products; 2) address the barriers presented by the current requirements for updating drug product expiration dates in labelling; and 3) advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products, which is sometimes provided by the manufacturers themselves.

3. Primary and Preventive Care

To discontinue ASHP policy 9407, which reads:

- 1 To support primary and preventive care roles for pharmacists in the provision of
- 2 pharmaceutical care; further,
- 3 To collaborate with physician, nursing, and health-system administrator groups in
- 4 pursuit of these goals.

Background

The Council discussed ASHP policy 9407 as part of sunset review. The Council determined that the policy is redundant with the [ASHP Statement on the Pharmacist's Role in Primary Care](#) and voted to recommend discontinuation.

4. Nondiscriminatory Pharmaceutical Care

To discontinue ASHP policy 9006, which reads:

- 1 To adopt the following positions in regard to nondiscriminatory pharmaceutical care:
 - 2 • All patients have the right to privacy, respect, confidentiality, and high-
 - 3 quality pharmaceutical care.
 - 4 • No patient should be refused pharmaceutical care or denied these rights
 - 5 based solely on diagnosis.
 - 6 • Pharmacists must always act in the best interest of individual patients while
 - 7 not placing society as a whole at risk.

Background

The Council discussed ASHP policy 9006, Nondiscriminatory Pharmaceutical Care, as part of sunset review. The Council presumed that the policy was created to respond to concerns that patients with human immunodeficiency virus infection and acquired immunodeficiency syndrome would be denied privacy, respect, confidentiality, and high-quality pharmaceutical care because of their diagnoses. The Council noted that treatment of those patients has been integrated into the mainstream of pharmacy practice, concluded that the policy is redundant with the [Code of Ethics for Pharmacists](#) and other ASHP policies (e.g., ASHP policy 0101, [Pharmacy Benefits for the Uninsured](#)), and voted to recommend discontinuation.

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.)

- Elimination of Apothecary System (8613)
- Tamper-Evident Packaging on Topical Products (9211)
- Pediatric Dosing Forms (9707)
- Interventions to Reduce High-Risk Behaviors in Intravenous Drug Users (9711)
- Appropriate Dosing of Medications in Patient Populations with Unique Needs (0228)
- Pharmacist's Role in Drug Procurement, Distribution, Surveillance, and Control (0232)
- Institutional Review Boards and Investigations Use of Drugs (0711)
- Electronic Health and Business Technology and Services (0712)
- ASHP Statement on the Role of Health-System Pharmacists in Public Health (0724)
- ASHP Statement on Professionalism (0725)
- ASHP Statement on Racial and Ethnic Disparities in Health Care (0726)
- Pharmacist Prescribing in Interprofessional Patient Care (1213)
- Pharmacist's Role in Accountable Care Organizations (1214)
- Pharmacist's Role in Team-Based Care (1215)
- ASHP Statement on the Pharmacist's Role in Medication Reconciliation (1227)

Other Council Activity

Joint Council Task Force on ASHP Position on Assisted Suicide

The Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy met as a Joint Task Force to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following a presentation and question-and-answer session, the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors.

Medical Cannabis

The Council voted to recommend that the Council on Public Policy consider amendments to ASHP policy 1101, Medical Marijuana. A total of [25 states, the District of Columbia, Guam, and Puerto Rico](#) now allow for comprehensive public medical cannabis programs. Healthcare providers in those jurisdictions, including pharmacists, are grappling with the challenges presented by medical use of medical cannabis (defined for purposes of this policy as whole or parts of the natural marijuana plant and therapeutic products derived therefrom). ASHP recognizes that there is some evidence supporting the effectiveness of medical cannabis to

treat or ameliorate symptoms of disease, including nausea and vomiting associated with cancer or its treatment with chemotherapy, lack of appetite associated with human immunodeficiency virus infection or acquired immunodeficiency syndrome, chronic pain, and pediatric epilepsy.

The Council agreed that there is need for research on best practices regarding management and use of medical cannabis, and suggested that ASHP could draw on member experience to offer education and guidance on the topic. The Council specifically recognized the potential importance of the medical cannabis model adopted by [Connecticut](#), in which only pharmacists may dispense medical cannabis.

Formulary Management

Discussions have begun with ASHP that formulary management is much different now than when many policies related to this topic were developed. ASHP is currently recruiting current third-year council members to participate on a formulary advisory panel. This group will review all current ASHP policies related to formulary management and determine the future direction of this topic.

COUNCIL ON PUBLIC POLICY

POLICY RECOMMENDATIONS

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

Ranee M. Runnebaum, *Board Liaison*

Council Members

Gloria P. Sachdev, *Chair* (Indiana)
Pamela Stamm, *Vice Chair* (Georgia)
Ewa Dzwierzynski (Rhode Island)
Tara Feller, *New Practitioner* (Maryland)
Chris Fortier (Massachusetts)
Erin Fox (Utah)
Carla Frye (Nebraska)
Mark Hamm (Ohio)
Melissa A. Ortega (Massachusetts)
Michael Powell (Nebraska)
Maria Serpa (California)
Danielle Thanh, *Student* (California)
Joseph M. Hill, *Secretary*

1. Partial Filling of Schedule II Prescriptions

- 1 To advocate that state legislatures and boards of pharmacy create consistent laws
- 2 and rules that discourage overprescribing by allowing partial filling of Schedule II
- 3 drugs; further,

- 4 To advocate that public and private entities construct criteria for partial filling to
- 5 minimize the additional practice burden on pharmacists and healthcare
- 6 organizations; further,

- 7 To advocate that pharmacists educate prescribers and patients about options for
- 8 filling prescriptions for Schedule II drugs, including the risks of overprescribing, while
- 9 recognizing the patient or caregiver's rights to make their own care and management
- 10 decisions.

Rationale

The issue of opioid abuse and addiction has been at the forefront of federal and state activity. Increasing addiction rates of patients taking powerful opioids have spurred calls for action to help address this growing problem. The issue has become national in scope and has generated discussion among policymakers and healthcare practitioners alike. In mid-2016, Congress passed the [Comprehensive Addiction and Recovery Act of 2016](#), legislation aimed at curbing opioid abuse and enhancing access to addiction treatment. States have been considering their own legislative initiatives to address what is increasingly described as an epidemic.

One solution proposed by policymakers is to allow pharmacists to dispense only a portion of the quantity of a Schedule II drug prescribed (e.g., 7 days of the prescribed quantity of the drug rather than an entire 30-day supply). Such "partial filling" of Schedule II drug prescriptions

reduces the potential of opioid addiction for the patient and the risk of diversion for others. Federal law has been changed to permit partial filling of Schedule II drugs, and Massachusetts and Maine have passed laws to allow for partial filling of Schedule II drugs. ASHP advocates that other state legislatures and boards of pharmacy amend pharmacy practice acts and rules to allow for partial filling of Schedule II drugs, and that such laws and rules be made consistent across states. However, ASHP has concerns about quantity and duration limits applied across the board and not on an as-needed basis. ASHP believes that each patient must be evaluated individually and that policies that allow for partial filling are not indiscriminately applied as an across-the-board mandatory rule. ASHP encourages public and private payers to recognize the additional practice burden created by partial filling and to provide appropriate reimbursement for those activities as well as minimize the additional practice burden where possible. ASHP encourages pharmacists to serve as patient advocates by educating prescribers and patients about options for filling prescriptions for Schedule II drugs.

Background

The Council discussed this topic in response to member interest. The Council reviewed [two related ASHP policies](#) (1520, Impact of Insurance Coverage Design on Patient Care Decision, and 1504, Patient Adherence Programs as Part of Health Insurance Coverage) that mention partial filling but which focus on medication safety and medication adherence rather than partial filling's role in reducing opioid diversion and addiction. The Council identified the need for ASHP to have policy supporting shorter filling cycles for Schedule II drugs. The Council also felt that pharmacists have a role in educating prescribers and patients to establish best practices regarding opioid prescribing and partial filling. Council members pointed out the potential for an increase in diversion if partial filling is abused (e.g., when only 7 days of a 30-day prescription are filled, an opportunity for diversion of the remaining quantity is created). The Council suggested that processes for ensuring that the rest of the prescription is voided may be a way to combat diversion under this scenario.

2. Restricted Drug Distribution

- 1 To oppose restricted drug distribution systems that (1) limit patient access to
- 2 medications; (2) undermine continuity of care; (3) impede population health
- 3 management; (4) adversely impact patient outcomes; (5) erode patients'
- 4 relationships with their healthcare providers, including pharmacists; (6) are not
- 5 supported by publicly available evidence that they are the least restrictive means to
- 6 improve patient safety; (7) interfere with the professional practice of healthcare
- 7 providers; or (8) are created for any reason other than patient safety.

(Note: This policy would supersede ASHP policy 0714.)

Rationale

Restricted drug distribution systems (RDDSeS) that are not created solely for patient safety reasons significantly restrict patient access to medications. These systems were justified as a means to closely monitor patient use of medications that could potentially pose a safety risk.

They were never intended to allow drug manufacturers to reduce pharmacists' access to medications through limited distribution networks. Using restricted distribution as a tool to gain marketplace advantage rather than for patient safety undermines the justification for such limited systems. ASHP opposes the use of RDDSes for anything other than patient safety and encourages the FDA or other appropriate authorities to investigate whether RDDSes are being used in a manner inconsistent with the original intent. In addition, RDDSes may compromise continuity of care or interfere with pharmacists' accountability for care to certain patient populations, such as when an RDDS prevents a patient's pharmacist from obtaining it. Some investigational drugs approved for marketing under an RDDS are no longer available for qualifying patients on admission through the institution, despite the institution having a history of managing the drug while it was investigational. Such circumstances force the patient to seek care elsewhere or require their and their healthcare providers to unnecessarily utilize additional resources to provide care. In addition, healthcare organizations, responsible for the total care of the patient, including maintaining the patient's medical records, may lose the established patient-care relationship when a patient must go to a specialty pharmacy for a drug it cannot access. RDDSes fragment the healthcare delivery system at a time when public and private payers are increasing incentives to integrate patient care.

Background

The Council considered ASHP policy 0714, Restricted Drug Distribution, in response to a recommendation from the Council on Pharmacy Management that the Council examine whether drug manufacturers are manipulating RDDSes (e.g., risk evaluation and mitigation strategies) to gain a marketplace advantage. The Council examined the background provided by the Council on Pharmacy Management and voted to recommend policy 0714 be revised to oppose restricted drug distribution systems that have pernicious effects rather than describe a set of criteria that would make such systems acceptable. ASHP policy 0714 reads:

To affirm support for the current system of drug distribution in which prescribers and pharmacists exercise their professional responsibilities on behalf of patients; further,

To acknowledge that there may be limited circumstances in which constraints on the traditional drug distribution system may be appropriate if the following principles are met: (1) the requirements do not interfere with the continuity of care for the patient; (2) the requirements preserve the pharmacist–patient relationship; (3) the requirements are based on scientific evidence fully disclosed and evaluated by prescribers, pharmacists, and others; (4) there is scientific consensus that the requirements are necessary and represent the least restrictive means to achieve safe and effective patient care; (5) the costs of the product and any associated product or services are identified for purposes of reimbursement, mechanisms are provided to compensate providers for special services, and duplicative costs are avoided; (6) all requirements are stated in functional, objective terms so that any provider who meets the criteria may participate in the care of patients; and (7) the requirements do not interfere with the professional practice of pharmacists, prescribers, and others; further,

To advocate that the Food and Drug Administration (FDA) be granted the authority to consult with practicing pharmacists and others when the establishment of a restricted distribution system is contemplated for a drug product; further,

To advocate that FDA be granted the authority to require that manufacturers disclose all of the considerations that led to the establishment of a restricted distribution system for a specific product; further,

To advocate that FDA be granted the authority to require that manufacturers include in each restricted distribution system a mechanism that will ensure medication reconciliation and continuity of care as patients transition from one level or site of care to another; further,

To advocate that FDA be granted the authority to require manufacturers to conduct a follow-up assessment of the impact of a restricted drug distribution system.

3. Collaborative Drug Therapy Management

- 1 To pursue the development of federal and state laws and regulations that authorize
- 2 collaborative drug therapy management by pharmacists; further,

- 3 To advocate expansion of federal and state laws and regulations that optimize
- 4 pharmacists' ability to provide the full range of professional services within their scope
- 5 of expertise; further,

- 6 To advocate for state laws and regulations that would allow pharmacists to transmit
- 7 prescriptions electronically under collaborative drug therapy management protocols;
- 8 further,

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

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

(Note: This policy would supersede ASHP policy 1217.)

Rationale

Although more than 43 states permit collaborative drug therapy management (CDTM), there is great variability in the authority granted to pharmacists engaged in CDTM. ASHP supports CDTM and advocates its expansion to all states, in a variety of diverse practice settings, and at the highest level of pharmacy practice. As new pharmacy practice models emerge, CDTM should be a part of those innovations. One of the common barriers to the highest level of CDTM is the prohibition of pharmacists transmitting prescriptions electronically under CDTM

protocols. The expansion of CDTM, including electronic transmission of prescriptions, will aid in moving the profession forward to the highest level of interprofessional, team-based practice and will enable pharmacists to practice at the top of their licenses, accountable to the patient and the team for medication-related outcomes.

Background

The Council reviewed ASHP policy 1217, Collaborative Drug Therapy Management, in response to a recommendation from the House of Delegates and voted to recommend amending it as follows (underline indicates new text; ~~striketrough~~ indicates deletions):

To pursue the development of federal and state ~~legislative and regulatory provisions~~ laws and regulations that authorize collaborative drug therapy management by pharmacists; further,

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

To advocate for state laws and regulations that would allow pharmacists to transmit prescriptions electronically under collaborative drug therapy management protocols; further,

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

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

While CDTM laws recognize the ability of pharmacists to prescribe in accordance with a CDTM agreement, e-prescribing systems consistently do not recognize pharmacists as prescribers, which is a barrier to pharmacist patient care. The delegates who proposed this topic felt that ASHP should advocate for state CDTM laws that include pharmacists as providers in e-prescribing systems to reflect pharmacists' patient-care roles under CDTM. As states update their CDTM laws and regulations to reflect modern care delivery, they must also account for the use of e-prescribing systems used by pharmacists as part of the CDTM agreement.

While the Council on Public Policy is responsible for developing policy related to state, federal, and local laws and regulations, this policy has implications beyond the scope of the Council. For example, although the policy calls for ASHP to advocate for state CDTM laws to account for pharmacists prescribing using the e-prescribing systems, it does not include any advocacy that software developers account for collaborative practice agreements where pharmacists are prescribing pursuant to protocol. Therefore, the Council felt that some additional action items by ASHP are warranted. The Council made the following recommendations:

- The Section on Pharmacy Informatics and Technology should work with electronic medical record providers to allow for pharmacists to use the e-prescribing systems in states where collaborative practice allows prescribing pursuant to protocol.
- ASHP should publish the National Provider Identifier (NPI) taxonomy sheet as a resource, making it available to members. The background documents the Council reviewed included a document that described a workaround with respect to e-prescribing systems. Council members felt that this workaround document could be a key element of a resource page created to educate pharmacists on e-prescribing systems and collaborative practice.
- ASHP should provide education to its members on obtaining NPI numbers and, in particular, educate state affiliates to encourage their members to obtain NPI numbers.

4. Greater Competition Among Generic and Biosimilar Manufacturers

- 1 To support legislation and regulations that promote robust competition among
- 2 authorized generic and biosimilar pharmaceutical manufacturers.

(Note: This policy would supersede ASHP policy 0222.)

Rationale

A healthy market for generic drug products and biosimilars increases patient access to drugs and lowers drug costs. ASHP recognizes several threats to the health of that market and advocates legislative and regulatory solutions: speeding FDA approval of generic drug applications, especially for lifesaving drugs; reducing drug monopolies by incentivizing competition for additional market entrants; targeting exclusivity protections to truly innovative products; and curbing abuse of risk evaluation and mitigation strategies (REMS). In 2015, the FDA faced a backlog of nearly 4,000 generic drug applications, with the approval process taking three years or more. ASHP advocates that the FDA be provided the resources needed to evaluate and approve generic drug applications in a safe and timely manner. ASHP also advocates government and market incentives to increase competition for expensive drugs where no competitors exist and encourage additional market entrants. ASHP has long recognized that agreements between generic and brand-name manufacturers when a product's market exclusivity is about to expire have the effect of delaying the marketing of competitor products and limiting patient access to affordable generic drugs. ASHP advocates for legislative and regulatory solutions to limit such agreements, as well as solutions to prevent brand-name manufacturers from extending market exclusivity and preventing market entry by generics by slightly altering the formulation of a product. ASHP further advocates legislation that would prevent frivolous patent infringement litigation by brand-name manufacturers, which is reported to have been initiated with the sole intent to extend market exclusivity. Another solution advocated by ASHP is curbing misuse of REMS, which are reported to have been used to prevent generic manufacturers from accessing drug products. In addition, ASHP advocates

for more consumer-accessible information on drug prices, including an annual report on increases in drug prices, which would provide patients and their healthcare providers with the information they need to make drug purchasing choices. Finally, ASHP encourages [appropriate federal review of anticompetitive practices](#) by pharmaceutical manufacturers.

Background

The Council reviewed ASHP policy 0222, Greater Access to Less Expensive Generic Medications, and voted to recommend amending it as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To support legislation and regulations that promote ~~greater patient access to less expensive generic drug products~~ robust competition among authorized generic and biosimilar pharmaceutical manufacturers.

The Council discussed this topic at length and considered changes to it given recent changes in the marketplace and the impact that skyrocketing drug prices have had on hospital pharmacy budgets and patient access to care. The Council felt that the pharmaceutical industry has been thwarting competition that would help drive down prices. The Council cited practices such as pay for delay, where a brand name company pays a fee to a potential generic competitor to stay out of the market for a certain period of time. In its discussion, the Council noted the need for transparency, patient choice in therapeutic alternatives, and patient knowledge of drug costs. Transparency was discussed within the context of research and development costs and the source of funding for research and development, such as the National Institute of Health. Further, the Council discussed transparency in how prices are developed and how manufacturers justify the value of their products. Ultimately, the Council kept the policy language broad, with a focus on competition and value. Both competition and value are contained in the policy platform of [the Campaign for Sustainable Rx Pricing \(CSRxP\)](#), a broad coalition of stakeholders including payers, clinicians, hospitals, retailers, and seniors. The CSRxP was formed to help address the growing problem of skyrocketing drug prices. The Council voted to include these two broad policy objectives in the new policy language. The third policy platform item developed by CSRxP, transparency, was left out of the policy over concern that transparency could extend to contract pricing and negotiated transactions that are considered proprietary in nature.

The Council also discussed steps that pharmacists can take to help alleviate the problem. Therapeutic substitution has long been used by pharmacists to give patients access to less expensive generic medications. The Council reaffirmed its support of therapeutic substitution. Additionally, the Council recommended that the rationale for this policy refer to existing ASHP policy 0814, [Federal Review of Anticompetitive Practices by Drug Product Manufacturers](#). This policy opposes anticompetitive practices by manufacturers that adversely affect drug product availability and price.

5. Drug Testing

- 1 To recognize the use of pre-employment and random or for-cause drug testing during
- 2 employment based on defined criteria and with appropriate testing validation
- 3 procedures; further,

- 4 To support employer-sponsored drug programs that include a policy and process that
- 5 promote the recovery of impaired individuals; further,

- 6 To advocate that employers use validated testing panels that have demonstrated
- 7 effectiveness detecting commonly abused or illegally used substances.

(Note: This policy would supersede ASHP policy 9103.)

Rationale

Controlled substance diversion and abuse has reached the attention at the highest levels in the U.S., with even the White House weighing in on the crisis. In the past 4-5 years, the Drug Enforcement Administration has levied large fines on chain drugstores, drug wholesalers, and even major hospitals. Pharmacy managers and pharmacists-in-charge have increasing responsibility of ensuring controlled substance management and storage across large healthcare organizations. There is an increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and many challenges exist for healthcare institutions in managing controlled substances.

ASHP recognizes that drug testing job applicants and employees whose responsibilities may bring them into contact with controlled substances is an essential element of diversion prevention programs. Pre-employment and random or for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances. In addition, drug testing should be supported by an employee addiction recovery program, as outlined in the [ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance](#).

Background

The Council reviewed ASHP policy 9103, Drug Testing, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text):

To recognize the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

The Council found the policy to still be relevant but voted to amend the policy to support healthcare organizations who wish to conduct random drug screening as part of a diversion control program.

The Council on Pharmacy Management recommended adding two additional items to the policy. The first was language to specify the use of validated testing panels that have demonstrated effectiveness in identifying the presence of substances commonly abused. The Council voted to accept that addition. The second was a suggestion that a positive employee drug test should trigger a follow-up test for infectious disease. The reasoning was based on an event in which a healthcare practitioner who was abusing controlled drugs placed used needles into inventory. The employee had hepatitis C, and the re-used needles eventually infected patients who used the same needles. The Council considered this addition but decided against including it in this amended policy. The Council agreed on the need for additional infectious disease screening but concluded that such testing was something that should be addressed in the healthcare organization's drug diversion policies and procedures rather than its drug testing policy. This decision was communicated to the Chair of the Council on Pharmacy Management, who agreed that this provision was more appropriate in a drug diversion policy.

6. Codes on Solid Dosage Forms of Prescription Drug Products

To discontinue ASHP policy 8709, which reads:

- 1 To support efforts requiring manufacturers of solid dosage form prescription drug
- 2 products to imprint a readily identifiable code indicating the manufacturer of the drug
- 3 product and the product's ingredients; further,
- 4 To make information on translation of the codes readily available.

Background

The Council reviewed ASHP policy 8709 as part of sunset review and concluded that it is no longer needed as federal law ([21 C.F.R. § 206.10](#)) reflects this policy. The Council noted the pharmacist or pharmacy may be required to print on the label a description of the imprint code and suggested that the appropriate ASHP council investigate whether ASHP policy regarding the requirement needs to be developed.

7. Intermediate Category of Drugs

To discontinue ASHP policy 0220, which reads:

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

5 To base such support on the following facts:

6 1. Some drug products that are potential candidates for switching from prescription-
7 only to nonprescription status raise concerns about patient safety as nonprescription
8 products; these products could be better controlled, monitored, and evaluated by
9 making them available only from pharmacists and licensed healthcare professionals
10 who are authorized to prescribe medications; and

11 2. Pharmacists have the education, training, and expertise to help patients make
12 appropriate therapeutic decisions associated with the use of such drug products.

13 Further,

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

16 Drug products appropriate for this intermediate category would be identified through
17 the advice of pharmacists, physicians, and other licensed health professionals who
18 are authorized to prescribe medications, on the basis of the medical conditions to be
19 treated and potential adverse effects (as indicated in FDA-approved labeling);

20 Pharmacists would be able to provide drugs in this intermediate category directly to
21 patients without a prescription, on the basis of appropriate assessment and
22 professional consultation;

23 Licensed health professionals who currently have prescribing authority would
24 continue to have the ability to prescribe medications in this intermediate category;
25 and

26 Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-
27 reaction reporting would be collected to help determine a drug product's eventual
28 movement to nonprescription status, return to prescription-only status, or
29 continuation in the intermediate category.

Background

The Council reviewed ASHP policy 0220 as part of sunset review and concluded that it is no longer needed because it is redundant with the [ASHP Statement on Criteria for an Intermediate Category of Drugs](#).

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.)

- Employee Testing (9108)
- Drug Samples (9702)
- Pharmacist Recruitment and Retention (0218)
- FDA Authority to Prohibit Reuse of Brand Names (0719)
- Standardizing Prefixes and Suffixes in Drug Product Names (0720)
- Pharmacy Technicians (1216)
- Stable Funding for HRSA Office of Pharmacy Affairs (1219)

Other Council Activity

Joint Council Task Force on ASHP Position on Assisted Suicide

The Council on Pharmacy Management, Council on Pharmacy Practice, and Council on Public Policy met as a Joint Task Force to consider ASHP policy 9915, ASHP Policy on Assisted Suicide, and the ASHP Statement on Pharmacist Decision-making on Assisted Suicide. Following a presentation and question-and-answer session conducted by [Dr. Mark Hughes](#), the Task Force discussed the policy and statement and recommended revising them. Members of the Task Force will review and comment on the draft revisions and then vote as a whole on recommending the resulting policy to the Board of Directors.

Medical Marijuana

The Council recommended that ASHP develop materials intended to help hospitals who come into contact with patients using medical marijuana. There are currently no guidelines on how hospitals handle patients who are using cannabis for medical purposes. The Council noted that there may not be a need for new policy but urged ASHP to explore options such as networking sessions or blinded surveys to gain an understanding of what, if anything, hospitals and health systems currently do. A recommendation made by the 2015 ASHP House of Delegates asked ASHP to examine ASHP policy on the regulation of dietary supplements. Relevant ASHP policies include 0801, 1305, 0920, 0811, and 0415.

The Council concluded that existing ASHP policy on the regulation of dietary supplements is adequate. One area of potential concern is the growing use of homeopathic medicines. After discussion, the Council decided that homeopathic medications are not entirely within the Council's purview and that the Council on Therapeutics may want to investigate this issue further.

Exploring Drug Pricing Transparency

The Council discussed this along with the issues raised above with respect to a marketplace that has robust competition. In lieu of the revised policy 0222, the Council felt that new policy that captures competition, transparency, and value should be explored. Additionally, the Council Chair urged this policy to be developed during this policy year.

Pharmacists in State Medicaid Programs

The Council reviewed several ASHP policies and identified two volunteers to further explore ASHP policy and draft potential policy language for consideration at a future meeting. Specifically, the area of interest is sustainability and reimbursement within Medicaid. The National Governors Association report from 2015 includes a table that outlines services and reimbursement provided by pharmacists in state Medicaid programs. The Council will explore policy that attempts to standardize services and reimbursement rather than create a patchwork of state rules in this area.

Medicaid Program and the Affordable Care Act (ACA)

The Council was informed that Congress is considering block granting Medicaid funding to states. One member suggested that ASHP explore a policy position that would describe the basic elements that Medicaid programs should provide. The Council discussed several options for sharing information with members about provider status recognition, state Medicaid programs, and ACA repeal and replacement. The Council concluded that a white paper would be the best option and should be discussed at the next internal ASHP policy meeting.

21st Century Cures Act

The Council requested that the Council on Therapeutics review the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control in light of the Act.

COUNCIL ON THERAPEUTICS

POLICY RECOMMENDATIONS

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

Donald E. Letendre, *Board Liaison*

Council Members

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Amy S. Sipe, *Vice Chair* (Missouri)
Karen Berger (New York)
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Katie Morneau (Texas)
Nathan Pinner (Alabama)
Jodi L. Taylor (Tennessee)
Mary Vincent, *New Practitioner* (Ohio)
Vicki Basalyga, *Secretary* (Maryland)

1. Therapeutic and Psychosocial Considerations of Transgender Patients

- 1 To support medication and disease management of transgender patients as a part of
- 2 care unique to this population; further,

- 3 To advocate that transgender patients have access to pharmacist care to ensure safe
- 4 and effective medication use; further,

- 5 To promote research on, education about, and development and implementation of
- 6 therapeutic and biopsychosocial best practices in the care of transgender patients;
- 7 further,

- 8 To encourage documentation of a patient's birth sex and identified gender in the
- 9 patient medical record.

Rationale

The transgender population is a small population that has unique healthcare and biopsychosocial needs. There are [guidelines](#) to help practitioners caring for the patients identify these needs and recommendations for practitioners to consider.

Patients electing to transition from their birth sex to their identified gender may have surgeries and take higher doses of hormones to change their physical appearance to reflect their identified sex. These patients have significant requirements for therapeutic drug monitoring, as certain lab values may appear out of normal limits but are clinically appropriate for the transgender patient and risk of drug-drug interactions may be higher because medications may be taken at a higher than normal doses. These patients may be more at risk for adverse effects,

including thyroid disorders, and may more frequently require anticoagulation and management of diabetes as a result of medication therapy. Other unique needs of these patients include cardiovascular and thrombotic risk assessment, screening for certain types of cancers should they elect to keep their gonadal organs, and other associated primary care screenings associated with their birth sex. Considerations for transgender patients who wish to have children will add the complexity of fertility as well as attention to use of teratogenic medications to their needs. Because of the unique and complex healthcare needs of transgender patients, it is essential that they have adequate access to appropriate care, including pharmacist care. To help ensure appropriate assessment and treatment, a patient's birth sex and identified gender should be documented in the patient medical record. This documentation also helps healthcare providers address another of the unique biopsychosocial needs of transgender patients; like other healthcare providers, pharmacists should address transgender patients by their identified gender.

Background

The Council discussed the definitions used in providing care to meet the unique clinical and social needs of transgender patients. A review of available research and guidelines revealed that there are no clinically significant changes in a person's pharmacodynamic or pharmacokinetic parameters when transitioning from birth sex to identified gender. In addition, the Council discussed the biopsychosocial aspects of caring for transgender patients. The Council reviewed recent cases in which addressing patients by the name associated with their birth sex during, despite requests to be called by the name associated with their identified gender, resulted in self harm and death. Finally, the Council discussed the discrimination transgender patients may face and the importance of access to care and of ensuring equitable care.

2. Pharmacist's Leadership Role in Glycemic Control

- 1 To advocate that pharmacists provide leadership in caring for patients receiving
- 2 medications for management of blood glucose; further,

- 3 To advocate that pharmacists be a member of the interprofessional healthcare team
- 4 that coordinates glycemic management programs; further,

- 5 To encourage pharmacists who participate in glycemic management to educate
- 6 patients, caregivers, prescribers, and other members of the healthcare team about
- 7 glycemic control medication uses, metrics, drug interactions, adverse effects, the
- 8 importance of adhering to therapy, access to care, and recommended laboratory
- 9 testing and other monitoring.

Rationale

As medication experts, pharmacists play a key role in implementation, maintenance, monitoring, management of complications, risk assessment, and assurance of continuity of care for patients receiving medications for management of blood glucose. Inappropriate medication-related management of diabetes creates unnecessary, preventable harm. There is a direct relationship between medication administration and harm from inappropriately managed glycemic agents. In 2014, the [Accountability Measures Work Group](#) identified the incidence of hypoglycemic and hyperglycemic events and evidence of poorly controlled diabetes (hemoglobin A1C value exceeding 9%) as clinical measures for pharmacist accountability. Given this responsibility, pharmacists need to provide leadership in caring for patients receiving medications for management of blood glucose, including education of patients and members of the interprofessional healthcare team. To enhance their ability to participate in the care of these patients, many pharmacists have elected to become certified diabetes educators. This training strengthens the value of pharmacists and permits them to be more aligned with the benchmarking tools linked with reimbursement models. The unknown adverse effects of sustained hyperglycemia in the inpatient and outpatient settings, as well as during transitions of care, demonstrate a continued need for pharmacist-led research in both all settings.

Background

The Council created this policy after discussion of the 2014 [Pharmacy Accountability Measures Work Group](#) recommended clinical measures for pharmacy accountability. The Council reviewed all ASHP policies, statements, and guidelines and found there are no policies on glycemic control despite its identification by the Accountability Measures Work Group as one of four clinical measures for pharmacist accountability. The Council supported education and collaborative development of practice recommendations. The Council also recommended education through webinars or educational sessions, developing resources that address transition of care, encouraging research opportunities for ambulatory care pharmacists, and potential development of a best practices document or minimum standard regarding glycemic management.

3. Drug Dosing in Diseases That Modify Pharmacokinetics or Pharmacodynamics

- 1 To encourage research on the pharmacokinetics and pharmacodynamics of drugs in
- 2 acute and chronic disease states; further,

- 3 To support development and use of standardized models, laboratory assessment,
- 4 genomic testing, utilization biomarkers, and systemwide documentation of
- 5 pharmacokinetic and pharmacodynamic changes in acute and chronic disease states;
- 6 further,

- 7 To collaborate with stakeholders in enhancing aggregation and publication of and access
- 8 to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug
- 9 dosing within these patient populations.

Rationale

The pharmacokinetic and pharmacodynamic properties of drugs found in drug information monographs are based on the drug's absorption, distribution, metabolism, and excretion in healthy, adult patients during Phase I of a drug's clinical trials. Many patients receiving medication therapy do not fit this profile, and many have compromised organ function. The medical community has long recognized the need for a standardized approach to evaluating organ system dysfunction. Although there are methods to determine organ function (e.g., the Cockcroft-Gault equation for renal function or the Child-Turcotte-Pugh Classification for Severity of Cirrhosis), there is debate as to whether these methods are true indicators of organ function, as the components that comprise these equations may fluctuate based on severity and disease status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

In addition, with the exception of adjustments for renal dysfunction, there is not much information regarding dosage adjustment for specific medications. Many organ systems are involved in a drug's absorption, distribution, metabolism, and excretion. Hepatic effects, for example, are a risk area, as those effects are slower to be seen and have not been the subject of as much research, and the number of drugs affected are smaller in number than renally excreted drugs. Both acute and chronic aspects of disease may require monitoring and adjustment, including sepsis, encephalopathies, pregnancy, heart failure exacerbations, and cystic fibrosis, and certain protocols such as therapeutic hypothermia can also have clinically significant impact on a drug's pharmacokinetic and pharmacodynamic behavior. There is also need to promote research and utilization of biomarkers into practice, as these may reflect organ function and may provide pharmacists with a more complete clinical picture.

Background

The Council identified the need for a standardized approach for evaluating organ system dysfunction as well as the evolution of pharmacists' understanding of pharmacokinetics and pharmacodynamics, particularly the work of [Meindert Danhof](#), whose emerging pharmacokinetic and pharmacodynamic theoretical concepts include physiology-based models in which disease states play an important role.

4. Clinical Significance of Extremes of Weight and Weight Changes

- 1 To encourage pharmacists to participate in interprofessional efforts to ensure
- 2 appropriate patient height and weight are recorded in the patient medical record to
- 3 provide safe and effective drug therapy to patients who may fall outside normal
- 4 weight parameters or experience clinically significant changes in weight in a short
- 5 period of time; further,

- 6 To encourage drug product manufacturers to conduct pharmacokinetic and
- 7 pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes
- 8 of weight and weight changes to facilitate safe and effective dosing of drugs in these
- 9 patient populations, especially for drugs most likely to be affected by weight; further,

- 10 To encourage independent research on the clinical significance of extremes of weight
11 and weight changes on drug use, as well as the reporting and dissemination of this
12 information via published literature, patient registries, and other mechanisms;
13 further,
- 14 To advocate that clinical decision support systems and other information
15 technologies be structured to facilitate prescribing and dispensing of drugs most
16 likely to be affected by extremes of weight and weight changes.

Rationale

Patients who have clinically significant changes in weight during an admission or between physician visits, or who are at an extreme high or low weight, have a higher risk of medication dosing errors that depend on weight body surface area. Accurate heights and weights in SI units (i.e., kilograms, grams, meters, and centimeters) are an integral part of a physical examination for pharmacists to ensure proper dosing of medications. Certain medications require dosing based on body surface area, and there is a need for healthcare organizations to consistently record patients' height, as estimation of height or weight can contribute to potential over- or underdosing.

Factors such as clinically significant changes in weight due to fluid overload and subsequent diuresis, patient growth, and weight changes due to changes in caloric consumption complicate the picture of an appropriate weight to record for dosing certain medications. Some healthcare organizations default to a dosing weight that is used for dosing medications alone, while other weight fluctuations recorded on a daily basis are not used to dose medications, whereas other organizations alert pharmacists to a clinically significant change in weight. Leveraging technology to ensure such safeguards are in place is essential, and providing interoperability between the patient's recorded dosing weight and smart pumps is ideal.

Pharmacists are also seeing an increase in the number of patients at both extremes of weight, and there is a lack of information regarding dosing medications for these populations. ASHP advocates that the Food and Drug Administration (FDA) develop guidance for voluntary drug dosing studies in these populations, as the need for this guidance is supported by the complexity of drug dosing that can vary based on drug and patient characteristics. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies, especially for drugs for which significant weight extremes may have clinical impact.

Background

The Council discussed the challenges of determining an appropriate dosing weight for patients and the inherent safety risk in changing a patient's weight too frequently, which can lead to dosing errors, especially when smart pumps are used to titrate vasoactive, pain, or antithrombotic medications. The Council also recognized that there are medications that do not

require dose changes even when there is a dramatic change in a patient's weight. The Council also encouraged ASHP advocate for independent clinical and practice-based research to further define clinical use of drugs in the treatment of these populations, as well as clinician reporting of patient experience in articles and clinical registries.

5. Pain Management

- 1 To advocate fully informed patient and caregiver participation in pain management
- 2 decisions as an integral aspect of patient care; further,

- 3 To advocate that pharmacists actively participate in the development and
- 4 implementation of health-system pain management policies and protocols; further,

- 5 To support the participation of pharmacists in pain management, which is a
- 6 multidisciplinary, collaborative process for selecting appropriate drug therapies,
- 7 educating patients, monitoring patients, and continually assessing outcomes of
- 8 therapy; further,

- 9 To advocate that pharmacists lead efforts to prevent inappropriate use of pain
- 10 therapies, including engaging in strategies to detect and address patterns of abuse
- 11 and misuse; further,

- 12 To foster the development of educational resources on multimodal pain therapy,
- 13 substance abuse and prevention of adverse effects, further

- 14 To encourage the education of pharmacists, pharmacy students, and other
- 15 healthcare providers regarding the principles of pain management.

(Note: This policy would supersede ASHP policy 1106).

Rationale

Currently there are over 100 million adults in the United States affected by acute and chronic pain. Pain management requires ongoing assessment and reassessment of analgesia, activities of daily living and adverse effects. Pharmacists are well poised to a key role in appropriate treatment and optimization of severe pain and chronic pain with multimodal treatment strategies. Pain therapies, in particular, have the potential for abuse if not used appropriately. ASHP is cognizant of the delicate balance between undertreatment of pain and barriers to patient access that can occur with the implementation of abuse-prevention strategies. ASHP advocates increased awareness of the abuse and misuse of some pain therapies and encourages pharmacists to take a lead role in identifying and preventing inappropriate use through individual clinician efforts (e.g., prescriber and patient education on the potential for

abuse) and system-based approaches (e.g., use of information technology systems to monitor for trends that suggest inappropriate prescribing or patient use).

Background

The Council reviewed ASHP policy 1106 as a part of the discussion of the clinical measures for pharmacy accountability recommended by the 2014 [Pharmacy Accountability Measures Work Group](#) and recommended amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

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

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects; further,

To encourage the education of pharmacists, pharmacy students, and other healthcare providers regarding the principles of pain management ~~and methods to minimize drug diversion.~~

The Council reviewed all policies, statements and guidelines by ASHP and recommending adding to policy 1106, language that addressed the role of multimodal pain therapy, substance abuse and prevention of adverse effects as these aforementioned areas are becoming increasingly present in management of pain. Furthermore, the Council also recommended removing mention of methods to minimize drug diversion, as this is addressed in ASHP policy 1614, [Controlled Substance Diversion and Patient Access](#).

6. Clinical Investigations of Drugs Used in Elderly and Pediatric Patients

- 1 To advocate for increased enrollment and outcomes reporting of pediatric and
- 2 geriatric patients in clinical trials of medications; further,

- 3 To encourage drug product manufacturers to conduct pharmacokinetic and
- 4 pharmacodynamic research in pediatric and geriatric patients to facilitate safe and
- 5 effective dosing of medications in these patient populations.

(Note: This policy would supersede ASHP policy 0229.)

Rationale

Pediatric and geriatric patients are populations in which the pharmacokinetic and pharmacodynamic properties of medications may differ from those typically seen in an adult patient. These differences can dramatically alter the behavior of drugs, producing supra- or subtherapeutic levels, which may result in adverse effects. While there has been legislation that provides incentive for drug manufacturers to study these effects, many drugs already approved by the FDA do not have such information or robust outcomes reporting for these at-risk populations. The need for this guidance is supported by the complexity of drug dosing for these patients, which varies based on drug and patient characteristics. A paucity of research in these patient populations is noted, which is similar to the lack of preapproval studies in obese patients. ASHP also encourages independent clinical and practice-based research to further define clinical use of drugs in the treatment of these patients, as well as clinician reporting of patient experience via published articles and clinical registries.

Background

The Council reviewed ASHP policy 0229 as part of sunset review and recommended amending it as follows (underline indicates new text; ~~strike through~~ indicates deletions):

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

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric and geriatric patients to facilitate safe and effective use of medications in these patient populations.

The Council found the policy relevant but concluded it needed to be updated and broadened to include outcomes reporting and to include trials of all medications rather than just new medications. The language used in ASHP policy 1515, [Research on Drug Use in Obese Patients](#), was adopted, as the Council concluded that this language captured the essence of the needed policy.

7. Safe and Effective Therapeutic Use of Invertebrates

- 1 To recognize use of medical invertebrates as an alternative treatment in limited
- 2 clinical circumstances; further,

- 3 To educate pharmacists, patients, and the public about the risks and benefits of
- 4 medical invertebrates use and about best practices for use; further,

- 5 To advocate that pharmacy departments, in cooperation with other departments,
- 6 provide oversight of medical invertebrates to assure appropriate formulary
- 7 consideration and safe procurement, storage, control, prescribing, preparation,
- 8 dispensing, administration, documentation, clinical and regulatory monitoring, and
- 9 disposal; further,

- 10 To encourage independent research and reporting on the therapeutic use of medical
- 11 invertebrates.

Rationale

Medical invertebrates, including leeches and maggots, are increasingly used in practice, including in treatment of extravasation injury, post-plastic-surgery salvage, relief of vascular congestion, macroglossia, compartment syndrome, pain management, and debridement therapy. The use of medical invertebrates is not without risk. There have been reports of local and systemic infections with use of leeches and transmission of communicable disease if not handled properly, and use may mask coagulopathies. Antimicrobial prophylaxis may be required, and there are also drug-invertebrate interactions that may impact the effectiveness of invertebrate therapy, and. There is also limited research on the efficacy of these therapies that lead to varied practice and unsubstantiated claims.

Background

There is a lack of evidence regarding many facets of leech and maggot therapy and lack of guidance regarding documentation in the electronic health record. There is also an absence of best practices regarding procurement, storage, use, and disposal of leeches and maggots. Many healthcare organizations that use medical invertebrates are storing, ordering, and utilizing leeches based on recommendations of the single source. These recommendations do not adequately cover appropriate indications for use, the ordering of leeches through an electronic medical record (EMR), or antimicrobial prophylaxis for medical leeches. Use of maggot therapy for debridement presents similar policy challenges. The Council identified the need for more education regarding appropriate patient selection (e.g., use for vascular congestion, not for ischemia or compartment syndrome) and management or avoidance of concomitant therapy (e.g., caffeine, vasoconstrictors). More research is also needed regarding the appropriate selection and duration of antimicrobial prophylaxis for medicinal leech therapy as well as the need for promotion of ordering medical leech therapy through EMR, which is needed for appropriate screening, documentation, and facilitation of adjunctive therapies. The Council also recognized the need for aid in developing policies for handling, sacrifice, and disposal. As with many nontraditional therapies, there are unsubstantiated healing claims of alternative medicine clinics and therefore, more research is needed on appropriate indications for use as well.

8. Drug Dosing in Extracorporeal Therapies

- 1 To encourage research on the pharmacokinetics and pharmacodynamics of drug
- 2 dosing in extracorporeal therapies; further,

- 3 To support development and use of standardized models of assessment of the
- 4 pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies;
- 5 further,

- 6 To collaborate with stakeholders in enhancing aggregation of data on the
- 7 pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies.

(Note: This policy would supersede ASHP policy 1606.)

Rationale

There are few resources and recommendations for drug dosing in patients receiving the varied forms of extracorporeal therapies, including renal replacement therapy, extracorporeal membrane oxygenation (ECMO) support, apheresis, plasmapheresis, molecular adsorbent recirculating system (MARS) support, single pass albumin dialysis (SPAD), fractionated plasma separation and adsorption (PROMETHEUS), therapeutic plasma exchange (TPE), extracorporeal liver assist device (ELAD) support, modular extracorporeal liver (MELS) support, peritoneal dialysis, and use of ventricular assist devices.

Appropriate dosing is a very important in optimizing patient outcomes and achieving goals of therapy. Often, drug properties are used to make educated guesses on appropriate dosing and are based on estimations of clearance. In the critically ill population, serious infections and renal issues often occur simultaneously. Solute removal has a significant impact on dosing and appropriate dosing. Many patient characteristics and device variables need to be considered when dosing patients receiving these therapies. These factors include flow rate, membrane pore size, volume of distribution, and patient status. Protein binding helps sustain the drug in tissue, and drugs with a large molecular weight may clog the porous membranes. There is a scarcity of research on drug removal by these extracorporeal means, and ASHP encourages independent clinical and practice-based research to further define clinical use of drugs for patients receiving these modes of treatment as well as clinician reporting of patient experience via published articles and clinical registries.

Background

A 2016 House of Delegates recommendation urged the Council to consider a policy to encourage research on drug removal by extracorporeal means to facilitate drug dosing support. The Council recognized that there are multiple modalities of extracorporeal support and treatment and concluded that ASHP policy 1606, Drug Dosing in Renal Replacement Therapy,

should be amended to include all extracorporeal modalities, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies ~~renal replacement therapy~~; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies ~~renal replacement therapy~~; further,

To collaborate with stakeholders in enhancing aggregation of data on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies ~~renal replacement therapy~~.

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.)

- Criteria for Medication Use in Geriatric Patients (1221)
- Medication Adherence (1222)
- Globalization of Clinical Trials (1223)

Other Council Activity

CPIC Guidelines

The Council voted to endorse the CPIC Guidelines on HLA-B Genotypes and Dosing of Allopurinol and the CPIC Guidelines on CYP3A5 Genotypes and Dosing of Tacrolimus.

The Council reviewed two [Clinical Pharmacogenomics Implementation Consortium](#) guidelines. The Council acknowledged that the development of these recommendations closely adheres to Institute of Medicine recommendations on developing rigorous and trusted clinical practice guidelines. The Council appreciated the focus on interpretation of genetic tests rather than appropriateness of testing. Previous councils have found value in this type of guidance to aid in practice.

Antibiotic-Impregnated Delivery Systems

The Council reviewed current ASHP policy to determine where it addressed practice issues related to antibiotic-impregnated delivery systems and concluded that the [ASHP Statement on the Pharmacist's Role With Respect to Drug Delivery Systems and Administration Devices](#), ASHP policy 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, and ASHP policy 1313, Drug-Containing Devices, address the topic to the Council's satisfaction but since much of this practice occurs behind closed doors, thought that high visibility is needed on the subject. The Council made the following recommendations.

- Stewardship Component: ASHP should advocate that antimicrobial stewardship programs ensure that antibiotics used in antibiotic bone cement or beads is documented in the medical record, including type and amount used, and monitored for resistance trends, management of shortages, and use.
- FDA and Manufacturers: ASHP should encourage manufacturers to make, and the FDA to approve, more commercially available products in concentrations commonly used in practice.
- Education, Tools, and Research: ASHP should promote awareness of the use of antibiotic-impregnated delivery systems through multiple channels, including webinars,

presentations at ASHP meetings, networking sessions, ASHP Connect, and the ASHP website. ASHP should also advocate for research on the non-FDA-approved drug/cement mixtures for stability and elution properties, evaluation of resistance trends, prolonged exposure, management of allergic reactions and/or adverse effects, and the use of impregnated cement for treatment versus prophylaxis.

- **Guidelines and Best Practices:** ASHP should reach out to a medical organization (e.g., American Academy of Orthopaedic Surgeons or Infectious Diseases Society of America) to develop best practices regarding use of antibiotic-impregnated delivery systems, including compounding, adverse drug events, and therapeutic monitoring and research. The Council further recommended reviewing the [ASHP Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery](#) to address and expand on the issues identified by the Council.

Pharmacist Accountability Measures: Antimicrobial Stewardship

The Council reviewed current ASHP resources and activities supporting the ASHP [Accountability Measures](#) for Antimicrobial Stewardship. After review, the Council made the following recommendations.

- **Recommendation to Council to Practice Management:** To consider developing policy to advocate for workforce changes to meet the anticipated need regarding adequate support of pharmacist time, resources, and staff to fulfill antimicrobial stewardship program activities. There is a concern that these requirements will overcommit pharmacists who already have a large workload and that there should be dedicated pharmacist resources for this role.
- **Recommendation to Council on Education and Workforce Development:** To consider developing policy to advocate that pharmacy schools consider antimicrobial stewardship as part of the educational curriculum.
- **General Recommendations:** ASHP should explore development of minimum competencies for pharmacist leaders and pharmacist participants, including development of a traineeship for pharmacist leaders with a mentorship component. ASHP should also explore resources to address the needs of institutions implementing an antimicrobial stewardship program.

Clinical Alternatives for High-Cost Drugs

The Council acknowledged that high drug costs are a multifaceted problem stemming from multiple causes, including single suppliers of both new and generic drugs. The Council noted the parallel discussion by the Council on Practice Management regarding this timely and important topic and agreed that the topic would best be addressed through a larger discussion among ASHP councils. The Council recognized that many of the aspects of the topic discussed were outside of the purview of the Council but suggested that they would be willing to serve as a resource to other councils on those issues. The Council observed that usage of high-cost drugs and drug shortages have similar effects, and that some of the strategies used to manage drug

shortages could be applied to managing use of high-cost drugs. The Council discussed strategies and made the following recommendations.

Management or Director Actionable Items

- Creation of a shortage/high-cost subcommittee as a component of pharmacy and therapeutic committees (this could be the subject of ASHP policy).
- Allocation of time and resources for more frequent medication-use evaluations for classes of medications on formulary when formulary items increase in price.
- Exploring reimbursement models that favor outpatient dispensing as a cost-saving measure.
- Creation of a high-cost drug policy or standards on managing high-cost drugs.

Clinical Decision-making

- Creation and maintenance of internal anticipatory recommendations for major drug classes would be ideal.
- Working with informatics pharmacists and licensed practitioners to develop temporary restriction protocols that trigger pharmacist consults on high-cost drugs.
- Transition of care upon discharge.
- Optimizing dosing, route, and frequency of administration for high-cost drugs with licensed practitioners.

Informatics

- Leveraging technology to assist in identifying changes in drug prices, alerting responsible clinical and management parties, as early identification is important.
- De-identifying resolved pricing issues is also important.

General Recommendations

- Creation of a toolkit of strategies or best practices for mitigating high-cost drug prices through informatics, clinical decision-making, and management strategies.
- Advocate for ethical and equal distribution of medications, as some patients have not been able to obtain a drug because their institution is not in the correct tier to receive a certain drug product.
- Creation of a community or forum that addresses decreasing waste, encourages transparent and collaborative efforts to assist in therapeutic change recommendations, ethical considerations, and post-marketing surveillance.
- Engaging leaders in the field to raise awareness of the impact of high drug costs through ASHP communication tools such as *AJHP* editorials and ASHP Connect blogs.
- Creation of education on the basics of formulary management as well as informatics best practice on management of shortages and high-cost drugs.

House of Delegates

REPORT OF THE COMMITTEE ON RESOLUTIONS

June 3, 2017

Minneapolis, Minnesota

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

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

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

Pursuant to the above article, the Committee on Resolutions presents the attached resolution to the House of Delegates. The recommendation of the Committee is to **not adopt the resolution**. Although the Committee supports the resolution's intent, a recommendation to not adopt was made because the Committee concluded that Council on Public Policy Recommendation 2, Restricted Drug Distribution, was a better means to achieve the outcome sought in the resolution. The Council's policy recommendation reads:

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

The Committee noted that the policy recommendation, approved by the Board of Directors in January and currently before the House, opposes "restricted drug distribution systems...created for any reason other than patient safety." The resolution does not recommend any restrictions on the criteria to be developed by the Food and Drug Administration (FDA) for defining specialty drug products. The Committee agreed with the Council's reasoning that restricted drug distribution systems may be justified as a means to improve patient safety by encouraging close monitoring of patients using especially dangerous drugs. The Committee further noted that the FDA currently has the authority to establish Risk Evaluation and Mitigation Strategies (REMS), which the policy recommendation envisions as the sole means FDA would have to establish a restricted drug distribution system, and that FDA only has authority over restricted distribution systems within the REMS program. The Committee felt it was not in the best interest of patients and providers to extend FDA authority over restricted distribution systems beyond the REMS program. The Committee concluded that the Council's policy recommendation was a better means to achieve the outcome sought in the resolution (to empower ASHP "to advocate for tightened control on specialty drug products that are only available through specialty pharmacies and a restricted drug distribution system") and that it should therefore recommend against adoption of the resolution.

Delegates are reminded that they are voting on the substance of the resolution, which is approval of the motion "To advocate that the Food and Drug Administration establish criteria for categorizing specialty drug products that will only be available through a restricted drug distribution system." The options for House action on the resolution, to be taken at the second meeting, are to (a) approve the

motion; (b) defeat the motion **(the option recommended by the Committee on Resolutions)**; (c) refer the motion for further study by a committee or task force to be determined by the Board of Directors; or (d) amend the resolution, which would then require due consideration by the Board of Directors at its next meeting in September.

Resolution for 2017 ASHP House of Delegates: FDA Criteria for Specialty Drug Products Available through Restricted Drug Distribution**Submitted By:**

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Subject: FDA Criteria for Drug Products Available through Restricted Drug Distribution

Received: March 3, 2017

Motion:

To advocate that the Food and Drug Administration establish criteria for categorizing specialty drug products that will only be available through a restricted drug distribution system.

Background:

Specialty medications are only available through limited distribution channels and provide a unique challenge to health-system pharmacy. Although only about 1% of all prescriptions today are for specialty medications, their cost is much higher than traditional medications. By 2020 it is expected that specialty medications will make up nearly half of the expenditures of all medications sold.^{1,2} Currently, the pharmaceutical manufacturer determines when a drug product will only be made available through a specialty pharmacy or restricted drug distribution channels. In most cases, specialty medications are for a niche patient population and require safety measures, patient education, and monitoring that go above and beyond what a traditional community pharmacy can provide. When a patient receiving a specialty medication is admitted to a hospital, the hospital is unable to order the medication from the specialty pharmacy, but instead relies on the patient to bring the medication to the hospital with them.

Limiting the availability of medications through specialty distribution channels provides a number of challenges to the health-system pharmacy. First, when a patient brings his or her own medication to the hospital, the chain of custody for the medication is unavailable to the health-system pharmacy and the pharmacy department is unable to verify the integrity of the drug product. Second, if the medication is to be administered by the health-system care providers, an administration fee can be charged but the health-system must be careful not to charge the patient for the medication itself since the patient has already paid for it. Third, if the health-system care provider wants to initiate a specialty medication while a patient is in the hospital, the complicated process for ordering and receiving the specialty medication is likely to result in a delay in therapy if it is even possible for the

pharmacy department to order and receive the medication. Finally, although it is possible for health systems to establish their own specialty pharmacies, this is a labor- and cost-intensive process and doesn't guarantee that the institution will be provided access to all specialty medications that their patients may need.

The number of specialty medications is growing at a projected rate of 20% per year. Some health systems refuse to allow patients to bring specialty drug products into the hospital because of the challenges in managing and administering a medication that did not go through the usual supply chain process. But this can jeopardize patient care. Pharmaceutical manufacturers currently determine, based on their own criteria, whether a new medication will be considered a specialty drug product and what distribution channels will be used. The Food and Drug Administration (FDA) does not have an official definition or designation for this class of drugs. The cost of specialty drugs is generally much higher than traditional medications – as high as \$750,000 per year, with the specialty pharmacy handling often considered one of the reasons justifying the high cost.³ Despite the lack of a consistent definition of a specialty drug product, insurers have a number of strategies in which they attempt to limit use of these expensive medications, such as using a specialty drug cost tier, limiting patients to receiving a 30-day supply after a first fill limit of 1-2 weeks, requiring prior authorization, among others.⁴ By developing FDA criteria for when a drug product would only be available through specialty pharmacies and a restricted drug distribution system, the number of drugs in this category could be minimized and there would be assurance that only the most critical medications would be included.

References

1. Edlin M. Top pharmacy challenges of 2017. *Managed Healthcare Executive*. 2017;27(1):23-25.
2. Our 2020 Outlook for Specialty Pharmacy Revenues. 2016, April 21. Retrieved from <http://www.drugchannels.net/2016/04/our-2020-outlook-for-specialty-pharmacy.html>
3. Herrick DM. Specialty drugs and pharmacies. National Center for Policy Analysis. Policy Report No. 355. 2014, May 22. Retrieved from <http://www.ncpa.org/pdfs/st355.pdf>
4. Kirchhoff SM. Specialty drugs: background and policy concerns. 2015, August 3. Retrieved from <https://fas.org/sgp/crs/misc/R44132.pdf>

Outcome: ASHP to advocate for tightened control on specialty drug products that are only available through specialty pharmacies and a restricted drug distribution system.