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House of Delegates

Board of Directors Report: Policy Recommendations for the June 2018 House of Delegates

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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.

Lea S. Eiland, *Board Liaison*

1. Medication Formulary System Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; and (3) should not be based solely on economic factors.

(Note: This policy would supersede ASHP policy 0102.)

Rationale

A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and

cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

As described in more detail in the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System, a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the involvement of appropriate healthcare professionals, and are not based solely on economic factors.

Background

The Council reviewed ASHP policy 0102, Medication Formulary System Management, as part of ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Panel in making its recommendation discussed the importance of factoring comparative effectiveness considerations into the formulary decision process. It supports the premise that formulary decisions should not be made exclusively based on the cost of the medication. The Panel felt that comparative effectiveness is a different point of consideration than a pharmacoeconomic review. The Council voted to recommend amending policy 0102 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care;~~, and~~ (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; ~~further,~~
>
> ~~To declare that decisions on the management of a medication formulary system~~ and (3) should not be based solely on economic factors.

2. Manufacturer-sponsored Patient Assistance Programs

To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients, regardless of distribution channels; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drug products used in inpatient settings; further,

To encourage pharmacists, other patient care providers, and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

(Note: This policy would supersede ASHP policy 1420.)

Rationale

ASHP recognizes the value of patient assistance programs (PAPs) in improving continuity of care while controlling costs and advocates expanded use of these programs for uninsured and underinsured patients in ambulatory and inpatient care settings. Some organizations have demonstrated success in achieving the benefits of these programs through dedicated resources and a mastery of the many programs available. Simplification of these programs (similar eligibility criteria, a common data format) would reduce the resources required to participate and improve access and utilization. ASHP notes that while the number of PAPs in ambulatory care settings has increased, there has been little growth in programs for inpatients. Hospitals must then absorb the costs of patient care, which results in fewer resources in the overall healthcare system. ASHP believes that expansion of PAPs for high-cost drug products used for indigent inpatients would significantly offset some of the costs to hospitals and ultimately improve care. In addition, interprofessional cooperation will be needed to support patients in accessing drug products when the PAP doesn't cover the cost of the drug product due to high deductibles or co-pays. To ensure that these programs achieve their objectives, ASHP advocates that development of these programs ensure that they contain the elements of pharmacist patient care.

Background

The Council reviewed ASHP policy 1420, Manufacturer-sponsored Patient Assistance Programs, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Panel in making its recommendation suggested that PAPs should be available regardless of the source of the drug product (e.g., specialty pharmacy and limited distribution systems). The Panel also suggested that the rationale be amended to address instances in which the cost of the drug product is not entirely covered by the PAP due to high deductibles and co-pays. In addition, the Panel stated that pharmacists and pharmacy staff should facilitate patient access to PAPs; however, the Panel concluded that the focus of the policy should remain on advocating that manufacturers enhance access to PAPs. The Council voted to recommend amending policy 1420 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients, regardless of distribution channels; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drug products used in inpatient settings; further,

To encourage pharmacists, other patient care providers, and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

3. Product Reimbursement and Pharmacist Compensation

To collaborate with public and private payers in developing improved methods of reimbursing pharmacies for the costs of drug products dispensed, pharmacist services (e.g., compounding, dispensing, drug product administration, patient monitoring, and patient education), and associated overhead; further,

To educate pharmacists about those methods.

(Note: This policy would supersede ASHP policy 1304.)

Rationale

In well-intentioned efforts to reduce healthcare costs, public and private payers often seek to minimize the reimbursement to pharmacies for drug products. Historically, those reimbursements have sometimes exceeded the simple cost of the drug product to reimburse pharmacies for associated costs (e.g., storage, compounding, preparation, dispensing). Because cost-management efforts are likely to continue to reduce pharmacy reimbursement, other means of compensating pharmacies for those expenses will need to be found, and pharmacists will require education about those reimbursement methods. In addition, pharmacists and pharmacies need to be reimbursed for professional services associated with management of medications and related patient care.

Background

The Council reviewed ASHP policy 1304, Drug Product Reimbursement, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Panel in making its recommendation noted that there are new reimbursement mechanisms related to drug products that are not addressed in this policy. For example, reimbursement of administration and monitoring costs related to white bagging of medications, unused medications, 340B medications, and buy-and-bill programs. The Council

suggested a new title for the policy be considered, such as Product Reimbursement and Pharmacist Compensation, to capture the intent of the amendments that include cognitive and administration services. The Council voted to recommend amending policy 1304 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> ~~To pursue, in collaboration with public and private payers, the development of improved methods of reimbursing pharmacies for the costs of drug products dispensed, compounding and dispensing services, and associated overhead; further,~~
>
> To collaborate with public and private payers in developing improved methods of reimbursing pharmacies for the costs of drug products dispensed, pharmacist services (e.g., compounding, dispensing, drug product administration, patient monitoring, and patient education), and associated overhead; further,
>
> To educate pharmacists about those methods.

4. Patient Access to Pharmacist Care Within Provider Networks

To advocate for laws that would require healthcare payers, when creating provider networks, to include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits when delivered by other healthcare providers; further,

To advocate for laws that would allow a pharmacy or pharmacist to participate as a provider within a healthcare payer's network if the pharmacy or pharmacist meets the payer's criteria for providing those healthcare services; further,

To acknowledge that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality and viability of healthcare services provided; further,

To advocate that healthcare payers be required to disclose to pharmacists and pharmacies applying to participate in a provider network the criteria used to include, retain, or exclude pharmacists or pharmacies.

Rationale

As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacists working in those settings increasingly find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to

profitably operate), but when creating provider networks, payers should include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits when delivered by other healthcare providers. To ensure equal treatment for healthcare providers, payers should be required to disclose to those applying to participate in a provider network the criteria used to include, retain, or exclude providers. When pharmacists obtain provider status, the infrastructure required to implement direct, independent patient care and billing for provider-based services needs to be in place and be accessible. Ensuring pharmacists and pharmacies have the opportunity to engage and have access to payers and payer networks will improve patient access to pharmacists' care.

Background

The 2016 Council reviewed the issue of pharmacist and pharmacy access to payers. This issue was studied for two purposes: (1) as part of an assessment of provider status readiness, and (2) in response to a number of reports that hospital and health-system pharmacies were experiencing site-of-care and payer carve-outs. The 2016 Council proposed a new policy that focused on any willing provider statutes, that policy recommendation was debated by the House of Delegates in June 2016. Because the policy recommendation was the subject of debate and extensive amendment, the ASHP Board of Directors and the House of Delegates referred the policy recommendation and its amendments to the 2017 Council for further study.

In making its recommendation, the Board noted the importance and complexity of the subject matter, the substantial changes made to the recommendation on the floor of the House, the ability of ASHP staff to advocate on the topic based on existing policy, and the flexibility of the ASHP policy process to bring a revised and duly considered policy recommendation to the House in the near future. The Board commended the Council on taking action on a topic that will grow in importance as pharmacists gain more independence in practice on the path to provider status. The Board also recognized and appreciated the thoughtful deliberation that delegates engaged in to refine the policy recommendation from what was proposed to what resulted from amendment. The scope of the amendments indicated the legal and regulatory complexities of the topic, as well as the potential consequences of successful advocacy, and suggested that a longer period of due consideration would be beneficial. The Board observed that some organizations have had a long and difficult history in developing policy on this topic and concluded that the additional effort devoted to developing well-crafted and thoroughly vetted policy would be worthwhile.

Key elements that were suggested through the additional review on the topic included:

- Policy and advocacy for professionals' and healthcare organizations' access to or participation in payer networks is a critical issue for reimbursement and financial sustainability.
- Acknowledgement that payers need the ability to control access to their networks for financial sustainability, quality, and, in some cases, to help ensure a provider network can exist (e.g., if each provider doesn't have sufficient patient volume to operate there could end up being no providers in an area or region).
- It was advised that any willing provider laws should not be pursued specifically and to consider broader language as this gives more flexibility in advocacy and avoids the direct

controversy on application and potential negative implications of any willing provider laws.

- The American Medical Association and the American Pharmaceutical Association have similar policies advocating for fair and reasonable payer access.

The Council through its additional review decided to remove specific focus on any willing provider statutes and to recognize the balance needed on payer needs as well as pharmacist and pharmacy providers.

5. Health Insurance Policy Design

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

To advocate that health insurance payers and pharmacy benefit managers provide public transparency regarding and accept accountability for coverage decisions and policies; further,

To oppose provisions in health insurance policies that interfere with established drug distribution and clinical services designed to ensure patient safety, quality, and continuity of care; further,

To advocate for the inclusion of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

(Note: This policy would supersede ASHP policy 1520.)

Rationale

Evolving practices by health insurers are negatively affecting patient care decisions and impacting the relationships between patients and their care providers. One common health insurance practice restricts management of and access to certain drugs to specialty suppliers. Another problematic practice is that certain drugs are not reimbursed by the insurer when used as part of the patient's hospital or health-system care. Medicare, for example, deems certain drugs as self-administered drugs (SADs), which are not reimbursed when provided to a patient because they are not considered integral to the reason for admission. These practices increase the number of patients that "brown bag" medications when they are admitted to a hospital to avoid being charged personally for the uncovered medications. ASHP has identified a number of concerns about these practices, including impact on continuity of care, integrity of the drug supply, and impacts on patient satisfaction and public perception of healthcare organizations.

It is the responsibility of the pharmacist to ensure the integrity of drugs used in the care of patients in the healthcare facility in which he or she practices. Having to verify products that

patients bring with them from multiple suppliers disrupts the care process. Having patients go unreimbursed for a medication because it was administered in and supplied by the healthcare organization is confusing to the patient and damaging to the patient–provider relationship. More broadly, lack of understanding of the differing payment systems in different care settings leads to public relations challenges. In addition, the lack of transparency regarding how payers make certain coverage determinations and apply performance penalties (e.g., direct and indirect remuneration fees) creates a significant challenge for healthcare providers as they care for patients.

ASHP advocates reforming these insurance practices. Coverage of medications should not interfere with the safe and effective provision of care and should recognize the responsibility of pharmacists to ensure product integrity for care provided where they practice. In addition, ASHP advocates that the Centers for Medicare & Medicaid Services, commercial payers, and others include hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

Background

The Council voted to recommend amending ASHP policy 1520, Impact of Insurance Coverage Design on Patient Care Decision, as follows (underscore indicates new text):

> To advocate that all health insurance policies be designed and coverage decisions made in a way that preserves the patient–practitioner relationship; further,
>
> To advocate that health insurance payers and pharmacy benefit managers provide public transparency regarding and accept accountability for coverage decisions and policies; further,
>
> To oppose provisions in health insurance policies that interfere with established drug distribution and clinical services designed to ensure patient safety, quality, and continuity of care; further,
>
> To advocate for the inclusion of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

The Council discussed ASHP policies related to insurance design and payer access and contracting with the purpose of the answering questions which have arisen regarding the practices of pharmacy benefit managers (PBMs) and whether there should be more transparency for patient care providers, advocates, and payers relying on the PBMs to provide services or dictate contractual terms. The Centers for Medicare & Medicaid Services (CMS) has increasingly become concerned about the impact of PBMs on Part D patients and taxpayers. CMS has begun to evaluate the impact of PBM transparency on beneficiary cost-sharing, Medicare subsidy payments, and plan liability. Additional areas of concern about the lack of transparency of PBMs include (1) maximum allowable cost (MAC) pricing (the upper limit that a PBM or drug benefit plan will pay for generic drugs and multisource brands), (2) direct and

indirect remuneration fees, (3) inflated payments for generics, (4) pay-to-play contracts between PBMs and manufacturers, and (5) narrowing networks. The Council concluded that policy 1520, Impact of Insurance Coverage Design on Patient Care Decision, addressed the issues of insurance design but lacked a pointed statement on the need for transparency and recommended an amendment to the policy position.

6. Pharmacy Accreditations, Certifications, and Licenses

To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,

To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidenced-based principles of patient safety and quality of care; further,

To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,

To advocate that health-system administrators, including compliance officers and risk managers, allocate the resources required to support medication-use compliance and regulatory demands.

(Note: This policy would supersede ASHP policy 1303.)

Rationale

Pharmacy leaders have years of experience managing the demands and challenges of ensuring that pharmacy services meet the standards of accreditation organizations. Until recently, this responsibility was predominantly achieved through accreditation by The Joint Commission (TJC) and compliance with state laws and Board of Pharmacy regulations, as well as with federal requirements (e.g., those of the Drug Enforcement Administration). Healthcare organizations with ambulatory care services (e.g., home infusion, specialty pharmacy, and durable medical equipment) have had to manage the additional accreditation process for these business units. Until recently, the number of accreditation standards pharmacy leaders needed to be knowledgeable about was limited. Three recent phenomena have increased this challenge for pharmacy leaders: (1) TJC is no longer the only accreditor for hospitals and health systems; (2) healthcare organizations are developing or acquiring new business units that have their own accreditation processes that need to be integrated into existing ones; and (3) new accreditation, certification, or licensure processes have been created for services and businesses pharmacy leaders are responsible for.

The expansion of healthcare organizations and the growth of the pharmacy enterprise are creating a new environment with multiple accreditors and regulators, creating the challenge of compliance with overlapping accreditation, certification, and regulatory standards. Examples include the Michigan Board of Pharmacy requirement to obtain certification to conduct compounding and the California Board of Pharmacy requirement that each IV hood must have its own pharmacy license. In addition, community pharmacy accreditation processes and standards are being implemented that pharmacy leaders need to consider as well.

ASHP recognizes the difference between certifications that are the sole responsibility of and have a direct impact on a pharmacy and certifications of a healthcare organization's service line (e.g., stroke or transplant services) that are the responsibility of the organization but have medication management components that need to be addressed by the pharmacy. Pharmacists and pharmacy departments are being challenged by a growing number of required accreditations, certifications, and licensures, which result in increased need for pharmacist-in-charge designations, workforce fatigue, and direct and indirect costs.

Background

The Council voted to recommend amending ASHP policy 1303, Proliferation of Accreditation Organizations, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,
>
> To advocate that ~~encourage~~ healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidenced-based principles of patient safety and quality of care; further,
>
> To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,
>
> To advocate that health-system administrators, including compliance officers and risk managers, allocate the resources required to support medication-use compliance and regulatory demands.

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.)

- Interoperability of Patient Care Technologies (1302)
- Clinical Decision Support Programs (1212)
- Technician-Checking-Technician Programs (0310)
- ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Regulatory Impact on Shared Services Development

The Council discussed shared services for multi-hospital organizations, and although not a new phenomenon, with the rapid growth of mergers and acquisitions over the past 10 years healthcare executives are more aggressively seeking ways to optimize efficiencies and increase standardization across these large enterprises. In tandem with this organizational focus, pharmacy executives are also leveraging shared services for their various models of owned, affiliated, and contracted multi-hospital systems. Moreover, this organizational focus brings the decision making to the forefront on what services will be the most effective and efficient as shared services as well as the associated compliance and regulatory requirements..

The Council recommended that ASHP create resources that provide guidance on areas including TPN management, automation fulfillment, centralized order verification, automated dispensing cabinet, order verification for non-24-hour sites, telehealth, community pharmacy services, supply chain storage, and centralized fill of clinics. The Council suggested a survey of multi-hospital health systems would be useful to determine the scope of shared services in the marketplace including lessons learned on licensures and certifications being acquired. It was also suggested ASHP evaluate state rules and laws that impact shared services (e.g., when one state licenses a central Rx as wholesaler and another as a pharmacy).

Role of Pharmacy Services in Micro-Hospitals

The Council discussed the development of micro-hospitals that are emerging across the United States, especially in the Western states, to fill gaps in care for both underserved and Medicaid patients in addition to well-insured patients. Micro-hospitals can be considered a middle ground between full-scale hospitals and ambulatory care, free-standing emergency departments, and urgent care sites. They are open 24/7, have 8-10 inpatient beds, and range in size from about 15,000 to 50,000 square feet. These micro-hospitals are best positioned to service low-acuity illnesses, and it is ideal that they are within 20 miles of a full-service hospital in case a higher level of care is warranted. In general, patients are not expected to stay greater than 48 hours, and if longer care is required, then transfer to a full-service hospital is likely needed.

The Council recommended that ASHP provide education for members on micro-hospitals and how state rules and accreditation and payer differences will interplay, including information around the emerging trends of care locations (e.g., micro-hospitals, free-standing EDs, surgical centers). The Council decided this should be a topic for further discussion during its winter conference call.

Pharmacist Role in Medication-Related Electronic Health Record (EHR) and Technology Build and Maintenance

The Council discussed the increasing complexity and adoption of electronic health records and technologies that rely on medication information or medication-related data and how it has become increasingly important to treat the building and maintaining of medication-related files, clinical decision support, and interfaces with the same level of accountability as direct patient care performed by healthcare professionals.

The Council noted that even though there are now many pharmacists trained in informatics and more than willing to complete the work, some healthcare organizations continue to outsource tasks to the EHR vendor or other outside parties. Healthcare organizations and pharmacy departments are fighting to be allowed to have hands-on involvement, often unsuccessfully, to the point where it has developed into a safety issue.

The Council reviewed ASHP's related policies and statements in responding to the House of Delegates recommendation to address the need for more specific policy addressing the need to incorporate pharmacists in leadership roles in providing oversight and accountability for

these medication-related technology and EHR activities. The Council agreed a more strongly worded policy to address the issues and patient safety concerns is needed. The Council, in collaboration with the Section of Pharmacy Informatics and Technology's Chair, decided these policies and statements need to be reviewed in aggregate and the Section will provide proposed language as needed.

Patient Stratification and Managing Pharmacist Workload for Optimal Outcomes and Value

The Council reviewed four purposes of patient stratification in managing the pharmacy: external benchmarking (i.e., comparison with pharmacies from other organizations); deployment of pharmacy resources; frontline staff patient prioritization tools; and internal benchmarking and performance metrics (e.g., for meeting pharmacy and organizational expectations, demonstrating value to organizational leadership, or avoiding cost and generating revenue).

The Council's discussion resulted in the following recommendations:

- Investigate the opportunity to develop best practices around clinical decision support, formulas, and tools for patient stratification for pharmacy purposes
- Consider amending ASHP policy position 1212, Clinical Decision Support Systems, to address methods for validating CDS data and metrics for continuous quality improvement, after verifying whether current ASHP statements or guidelines address the issues.
- Encourage additional research on outcomes and benchmarking with patient stratification and clinical work by pharmacists.

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.

1. Use of International System of Units for Patient-related Measurements

To advocate that the U.S. healthcare system adopt and only use the International System of Units (SI units) for all patient-related measurements and calculations; further,

To advocate that healthcare organizations use clinical decision support systems and equipment that allow input and display of patient-related measurements and calculations in SI format only; further,

To promote education in the use of SI units and the importance of using SI units to prevent medical errors.

Rationale

National healthcare, quality, and safety organizations have for years promoted the sole use of SI units for dosing and weight measurements. Errors in conversion from pounds to kilograms have caused two-fold overdosing and significant underdosing, particularly among pediatric patients, where even small dosing changes can have profound effects. Conversion to and from English units of volume (e.g., from milliliters to teaspoons) has long been identified as a source of dosing errors. These types of errors have been reported in all phases of the medication-use process (e.g., prescribing, preparation, dispensing, and administration) in all patient care settings.

Official labeling for U.S. drug products provides weight-based dosing only in SI units (e.g., mg/kg), so use of any other units introduces a risk of error. ASHP endorses national and institutional efforts to standardize the measurement and communication of patient weight using only SI units (i.e., grams and kilograms) but recognizes that other patient measures are sometimes used in dosing and other health-related calculations (e.g., body surface area, creatinine clearance, glomerular filtration rate, body mass index, or adjusted body weight). ASHP therefore advocates sole use of SI units by healthcare providers during prescribing, preparation, dispensing, and administration of medications in all patient care settings. To promote that practice, clinical decision support systems (e.g., electronic health record) and equipment (e.g., scales, stadiometers, infusion pumps) be structured to allow input and display of patient-related measurements and calculations in SI format only. Finally, education in how to use SI units, and about the importance of using SI units to prevent medical errors, will be required to overcome cultural resistance by healthcare providers, caregivers, and patients regarding SI unit use.

Background

The Council considered this topic as a companion to recently adopted ASHP policy 1721, Clinical Significance of Accurate and Timely Height and Weight Measurements, which endorses interprofessional efforts to ensure that accurate and timely patient height and weight measurements are recorded in the patient medical record. The Council concluded that advocating the sole use of SI units for weight measurements would promote the accuracy of weight measurement but recognized that adoption of that practice for other measures used in patient care would further the goal of reducing medical errors.

2. Availability and Use of Appropriate Vial Sizes

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste (e.g., multiple-dose vials or single-dose vials of differing doses); further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the appropriate use of single-dose, single-use, and multiple-dose vials.

Rationale

A 2016 study estimated that the U.S. may spend close to $2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Since that landmark study, policymakers, healthcare providers, and payers have been calling for action on vial sizes. The Centers for Medicare & Medicaid Services (CMS) has begun to require that billing for Part B drug products distinguish between claims for those received by a patient and those for discarded drug product, and the Office of the Inspector General (OIG) of the Department of Health and Human Services has initiated a study to determine the cost of such waste. Considerable savings could be gained if vial sizes

more closely matched doses, and one of the goals of the OIG study is to determine how much could be saved by using vial sizes available overseas that more closely match doses. As one analysis has pointed out, pharmacoeconomic analyses done in the U.S. typically do not incorporate leftover drug product in cost calculations, which may inflate cost-effectiveness ratios, and drug manufacturers may be exploiting that omission. In contrast, the United Kingdom National Institute for Clinical Excellence requires manufacturers to include the cost of leftover drug in manufacturers' submissions, and vials of two cancer drugs studied (bortezomib and pembrolizumab) contain 1 mg and 50 mg, respectively, in the U.K., and 3.5 mg and 100 mg in the U.S.

ASHP advocates that pharmaceutical manufacturers provide drug products in vial sizes that reduce drug waste (e.g., multiple-dose vials or single-dose vials of differing doses), and that regulators, manufacturers, and healthcare providers cooperate to develop and implement best practices for drug vial optimization.

Background

The Council considered this topic in response to a recommendation from the House of Delegates. As high drug costs and drug shortages continue to plague healthcare settings, there is heightened attention to the need for pharmaceutical companies to package products in containers, most typically vials, that more closely match the dose the patient may receive so there is less waste. Pharmacy budgets continue to draw scrutiny, and decreasing waste from single-dose vials would help alleviate costs while still serving patient needs. In addition, capturing the remaining product from vials is one method of addressing drug shortages.

Pharmacy departments have tried to institute operational changes to address the waste from vials, but these strategies often cannot be applied and the unused portion of drug in the vial is simply thrown away. One strategy that pharmacies employ is the use of a one-way dispensing spike that allows multiple doses to be drawn from only one vial puncture. This process is more often used by large pediatric institutions, in which vial sizes are often considerably disproportionate to patient doses. However, not all vials are conducive to using this method (e.g., when the surface area of the rubber stopper of the vial is too small).

3. Use of Closed-System Transfer Devices to Reduce Drug Waste

To recognize that peer-reviewed evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used with aseptic technique and following current sterile compounding standards; further,

To foster research on standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

Rationale

A 2016 study estimated that the U.S. may spend close to $2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Considerable savings are gained when the leftover contents of those vials are used. One practice that has shown promise in optimizing use of leftover drug product is the use of closed-system transfer devices (CSTDs) to facilitate the transfer of drug product from one reservoir to another. CSTDs provide a mechanical barrier that prevents the release of hazardous drugs and so have primarily been used throughout the medication-use process to minimize healthcare workers' exposure to hazardous drugs. CSTDs' mechanical barriers also prevent the ingress of environmental contaminants, however, which has prompted study of their ability to prolong the sterility and stability of drug product in vials. A growing number of studies have been generating data that indicate specific CSTDs have the possibility of maintaining sterility and extending in-use time when used under sterile conditions defined by United States Pharmacopeia Chapter 797. Although many of the approved CSTDs have an indication for use to prevent microbial ingress, with studied dwell times of up to 168 hours when maintained in an ISO Class 5 environment using proper aseptic technique, they do not have an explicit indication for extending the in-use time of drug products. Until the data from the studies can be validated and applied, standard-setting entities and regulators will not permit this practice. ASHP therefore advocates that the peer-reviewed evidence that supports the ability of properly used CSTDs to maintain sterility and extend in-use times be recognized, and that development of best practices for using CSTDs for drug vial optimization be encouraged.

Background

The Council considered this topic in response to a recommendation from the House of Delegates. In 2004, the National Institute of Occupational Safety and Health (NIOSH) defined a CSTD as a "drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system." Therefore, a CSTD is a medical device that has the potential to serve two important roles in medication preparation and administration. The first is to minimize healthcare worker and patient exposure to hazardous medications. For those institutions that handle hazardous medications, use of CSTDs is increasing and will eventually become an expectation. Currently, USP General Chapters 797 and 800 recommend that hospitals and health systems that prepare and administer hazardous medications should provide access to CSTDs. Second, with its potential to prevent ingress of microbes from the environment, CSTDs may serve to preserve the sterility of a medication in a single dose vial after puncture, rendering it sterile past the current 6-hour in-use time. The latter is an important consideration for institutions that seek to maximize the amount of drug available to be utilized through the extension of sterility of medication vial content. In fact, based on information from BD, the PhaSeal product information sheet estimates that "24% of hospitals that employ CSTDs use them to extend the dating of products as part of drug vial optimization programs."

Discussion among Council members demonstrated concurrence that CSTD use is already a standard for minimizing exposure to hazardous drugs and that it could become a standard for

maximizing drug vial optimization as well. Council members discussed the need for further study of these practices and for greater awareness among healthcare workers on proper handling and use of CSTDs but, in the meantime, urged immediate uptake for maximizing healthcare worker safety and careful evaluation for use in minimizing medication waste.

4. Collaborative Drug Therapy Management

To discontinue ASHP policy 9801, which reads:

> To support the participation of pharmacists in collaborative drug therapy management, which is defined as a multidisciplinary process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,
>
> To recognize that pharmacists participate in collaborative drug therapy management for a patient who has a confirmed diagnosis by an authorized prescriber; further,
>
> To recognize that the activities of a pharmacist in collaborative drug therapy management may include, but not be limited to, initiating, modifying, and monitoring a patient's drug therapy; ordering and performing laboratory and related tests; assessing patient response to therapy; counseling and educating a patient on medications; and administering medications.

Background

The Council discussed ASHP policy 9801 as part of sunset review. The Council determined that the policy is redundant with ASHP policies 1715, Collaborative Practice; 1005, Medication Therapy Management; and 0905, Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Drug Therapy Management, and is no longer needed.

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.)

- Code of Ethics for Pharmacists (9607)
- Medication Administration By Pharmacists (9820)
- Expression of Therapeutic Purpose of Prescribing (0305)
- Pharmacist Support for Dying Patients (0307)
- Education About Performing-Enhancing Substances (1305)
- Standardization of Intravenous Drug Concentrations (1306)

Other Council Activity

Guidance for Compounding Sterile Preparations in Short Supply

The Council considered a recommendation from the House of Delegates that ASHP develop guidance for healthcare systems for compounding sterile products that are in short supply or on backorder due to national shortages. The recommenders noted that healthcare systems across the U.S. are experiencing shortages of emergent medications and suggested that having guidance would ensure that healthcare facilities are acting in uniformity and with accurate scientific data for compounding these medications. The Council noted that ASHP has extensive policy regarding drug shortages and that the recommenders were seeking a how-to, tactical guide. Several Council members agreed to author an article for AJHP related to practical, operational experiences in addition to creating an informational document outlining algorithmic decision-making and tactics to use during drug shortages.

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff

representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Support for Stewardship Programs

The Council considered a recommendation from the House of Delegates that ASHP consider developing policy to advocate for dedicated pharmacy workforce to meet the needs of antimicrobial stewardship programs, including adequate support for the pharmacist time and related resources required to develop, implement, and sustain antimicrobial stewardship programs. The recommenders also suggested ASHP policy might be needed to address global stewardship issues, as other areas such as pain stewardship and other topics may arise.
The Council acknowledged that there is new pressure on hospitals and health systems to develop, implement, and sustain stewardship programs, particularly antimicrobial stewardship programs, given the 2017 Joint Commission standards. Further, the Council shares the recommenders' concern that the healthcare community may be asked to develop stewardship programs for other topics in the future.

The Council concluded that current ASHP policy, particularly the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control and the ASHP Statement on the Health-System Pharmacist's Role in National Health Care Quality Intitiatives, adequately addresses the immediate need for ASHP policy on 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.

Timothy R. Brown, *Board Liaison*

Council Members
Pamela Stamm, *Chair* (Georgia)
Chris Fortier, *Vice Chair* (Massachusetts)
Mary Durham, *New Practitioner* (North Carolina)
Ewa Dzwierzynski (Rhode Island)
Erin Fox (Utah)
Roy Guharoy (Missouri)
Mark Hamm (Ohio)
Janet Lee (Maryland)
Jeff Little (Kansas)
Meredith Oliver, *Student* (Mississippi)
Melissa A. Ortega (Massachusetts)
Michael Powell (Nebraska)
Joseph M. Hill, *Secretary*

1. ASHP Statement on Advocacy as a Professional Obligation

1 To approve the ASHP Statement on Advocacy as a Professional Obligation (Appendix A).

Background

This statement was originally suggested by the PAC/Grassroots Advisory Committee and was also a recommendation from the House of Delegates at the 2017 Summer Meetings. The Council discussed the statement and agreed that advocacy is a professional responsibility. The Council agreed that other health professions have developed similar statements on advocacy and that ASHP should do so as well. Further, the Council voted to recommend approval of the language as written. However, the Council also debated whether the statement should define advocacy and agreed that providing a definition was suitable, although the Council felt it to be more appropriate to put in the background rather than the statement.

The Council further recommended an *AJHP* article, op-ed, or themed issue on advocating for patients and better patient care. The *AJHP* issue could include the statement on advocacy as a professional responsibility but would be expanded to go above advocating for the profession to include advocating for patients as well. The Council noted that this statement is also in line with Goal 5 of the ASHP strategic plan. Finally, the Council suggested that all or a portion of the statement be listed within the advocacy portion of the ASHP website.

2. Direct and Indirect Remuneration Fees

To advocate that private payers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated claims; further,

To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.

Rationale

Direct and indirect remuneration (DIR) fees are a growing concern among pharmacies that dispense medications in a retail pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for the Centers for Medicare & Medicaid Services (CMS) to account for the true cost of the drug dispensed, including manufacturer rebates and pharmacy concessions. Often these rebates and concessions were unknown until the drug was dispensed and the claim adjudicated. Recently, a concerning trend has emerged in which pharmacy benefit managers (PBMs) charge DIR fees to pharmacy providers, applying their own plan performance measures as a way to assess fees on pharmacies dispensing covered Part D drugs. These fees are problematic for the following reasons:

- The fees are arbitrary and appear to result from an unintended application of measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied tend to be based on maintenance medications such as blood pressure or medications used to treat diabetes. These measures were never intended to be applied to specialty medications, or other specialized disease states such as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.
- PBMs are not required to define, justify, or explain to providers or to CMS the rationale or process for imposing their DIR fees.

Pharmacies providing specialty medications have been especially hard hit by DIR fees, due to the fee structure. DIR fees can be a flat rate (a fixed amount per dollar per claim) or a percentage (typically 3-9%) of the total reimbursement per claim. When the percentage-based structure is applied, the fees increase markedly for specialty drugs, which are typically much more expensive than maintenance medications.

Even more disturbing is that the fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment. Questions also remain as to whether Part D plan sponsors have the authority to assess DIR fees on pharmacies. There are no references to DIR fees collected on pharmacies in either the Medicare Modernization Act or corresponding CMS regulations.

DIR fees have led to higher cost-sharing responsibilities for Medicare beneficiaries, causing more of them to enter the Part D “donut hole” in which they are solely responsible for the cost of a drug. Because of higher costs, adherence rates tend to be lower among beneficiaries in the donut hole. These higher costs are a perverse result contrary to the very

reason DIR fees were created – passing savings onto beneficiaries.

Pharmacies are not alone in their concern. In January 2017, CMS published a fact sheet expressing concern over DIR fees and cited them as contributing to increased drug costs, beneficiary out-of-pocket spending, and Medicare spending overall. ASHP supports legislation that would address the problem of DIR fees. For example, H.R. 1038/S. 413, the Improving Transparency and Accuracy in Medicare Part D Drug Spending Act, would prohibit Medicare Part D plan sponsors from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D.

Background

In the spring of 2017, ASHP developed an issue brief that outlined concerns and made a recommendation that ASHP advocate to prohibit or limit DIR fees. The issue brief and plan of action were approved by the Board of Directors at its April 2017 meeting. At the 2017 Summer Meetings, a member of the House of Delegates made a recommendation for the Council on Public Policy to develop policy on DIR fees. The Council added this to its agenda but also discussed on the July 2017 conference call whether the policy should be expanded to include pharmacy benefit management (PBM) transparency as a whole. It was noted that the Council on Pharmacy Management is exploring policy on PBM transparency and that the DIR issue is focused specifically on pharmacy reimbursement rather than the larger issue of transparency. Therefore, the Council felt that policy specifically around DIR fees should be developed, and that the larger issue of PBM transparency should proceed in the Council on Pharmacy Management. The Council also factored the decision by the ASHP Board to proceed with advocacy around the DIR issue to warrant the need for DIR-specific policy. As originally drafted, the new policy language focused on the Medicare Part D program; however, the Council did note that the issue could be about more than Part D drugs. The final recommendation was to get rid of the part D reference and not limit the policy to PBMs, thus keeping the policy broad.

3. Impact of Drug Litigation Ads on Patient Care

To oppose drug litigation advertisements that could lead patients to modify or discontinue therapy without consulting their providers; further,

To advocate that drug litigation advertisements that may cause patients to discontinue medically necessary drugs be required to provide a clear and conspicuous warning that patients should not discontinue drugs without seeking the advice of their healthcare provider.

Rationale

Many law firms use advertising as a means to generate clients for future litigation, including litigation regarding drugs. These advertisements can generate unnecessary fear for patients taking those drugs and may lead them to discontinue medically necessary therapies. Abruptly discontinuing a drug without consulting a healthcare provider can lead to failed therapy and

other adverse effects (e.g., some drugs require a tapered withdrawal to be safely discontinued, and patients on multiple medications may require new dosing or drug interaction assessments). Other than truth-in-advertising laws, there is currently no oversight of these advertisements and no requirement to warn patients about the potential harmful effects of discontinuing their drugs. ASHP agrees with the American Medical Association that such ads should be required to have clear and conspicuous warnings that direct patients to speak with their healthcare providers before discontinuing any drug.

Background

This policy recommendation was made at the 2017 Summer Meetings from the House of Delegates. The initial recommendation was to ban 1-800-Bad-Drug ads. The Council discussed this potential new policy and decided that it would not be appropriate to develop policy advocating for an outright ban on the ads. The Council was concerned that such a ban would not survive a constitutional legal challenge that it would impede the right to free speech. Instead, the Council drafted new policy language that opposes the ads unless a certain condition is met. The condition is that the ads must include conspicuous notification urging patients not to discontinue therapy without first talking to their provider. The Council voted to recommend the policy language above as new ASHP policy.

4. Approval of Biosimilar Medications

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

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

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

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

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

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; further,

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

To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA; further,

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

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

(Note: This policy would supersede ASHP policy 1509.)

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. The FDA approved its first biosimilar application in March 2015 for filgrastim-sndz, and others (e.g., adalimumab-adbm, adalimumab-atto, bevacizumab-awwb, etanercept-szzs, infliximab-abda, infliximab-dyyb) have followed.

At the state level, legislation has been proposed and enacted requiring patient and/or prescriber notification that a biosimilar medication has been interchanged. It is important to note that pharmacists cannot substitute a biosimilar medication unless the FDA has deemed that biosimilar to be interchangeable. As of 2017, 35 States and Puerto Rico have passed biosimilar substitution laws.

In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, Georgia's biosimilar law requires the pharmacist to notify the prescriber within 48 hours of dispensing the medication (excluding weekends and holidays).

ASHP supports legislation and regulation that would authorize the FDA to determine the interchangeability of biosimilars, thus permitting the substitution of biosimilars for the reference product without the intervention of the prescriber. Further, ASHP opposes the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance and opposes any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed. FDA's determination of interchangeability should be all that is needed in order to substitute the biosimilar with the reference product. Although FDA guidances are distinct from FDA regulations, they often have profound impacts on healthcare decisions and delivery, so ASHP encourages the FDA to include healthcare practitioners in their development.

ASHP recognizes that postmarketing surveillance and pharmacist evaluation as part of the formulary system before biosimilar use are required to guarantee safe use of biosimilar medications. ASHP also advocates for adequate reimbursement for biosimilars approved by the FDA.

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to amend ASHP policy 1509, Approval of Biosimilar Medications, as follows (underline indicates new text; ~~strikethrough~~ indicates deleted text):

> To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,
>
> To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,
>
> To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications; further,
>
> To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted for the reference product without the intervention of the prescriber; further,
>
> To oppose the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance; further,
>
> To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,
>
> To support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; further,
>
> To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,
>
> To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA ~~deemed interchangeable~~; further,
>
> To promote and develop ASHP-directed education of pharmacists about biosimilar medications and their appropriate use within hospitals and health systems; further,
>
> To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

In making its recommendation, the Advisory Panel discussed several considerations and perspectives related to this policy and biosimilars overall. Biosimilars represent a seismic shift in the medication use and care delivery process; pharmacists must be prepared to lead on any

regulatory, reimbursement, or patient care activity related to them. Also, the pace in which policies and practice changes are being considered related to biosimilars demands that this policy be reviewed and updated frequently in order to adequately capture current knowledge base and trends in the market. The addition of language related to FDA guidances, current and anticipated, was added because the policy was currently silent on the topic. While FDA guidances are distinct from FDA regulations, they have and will have a profound impact on health care decisions and delivery. The Panel also felt that there needs to be adequate reimbursement for all biosimilar medications that are submitted and approved through 510(a) and 510(k) pathways, independent of whether that biosimilar is deemed interchangeable.

5. 340B Drug Pricing Program Sustainability

To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate with state Medicaid programs to ensure that reimbursement policies promote 340B program stability; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; further,

To encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

(Note: This policy would supersede ASHP policy 1407.)

Rationale

Statutory and other policy changes to the federal drug pricing ("340B") program in recent years have spurred an increase in the number of hospitals and other eligible entities that participate. Since the program's inception, the number of 340B-eligible and participating hospitals has continued to grow. Policymakers and other stakeholders have raised questions about the integrity of the program as well as its original intent. In addition, compliance with the current program continues to be challenging. Specifically, clarification to existing policy guidance or via newly proposed regulation is needed with respect to various issues. These include the definition of a patient, use of contract pharmacies, eligibility by various hospitals, and use of group purchasing organizations to purchase drugs for inpatient and outpatient use. Moreover, expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) allowed additional hospitals to participate in the program, further driving scrutiny and questions from policymakers and stakeholders. In response to policymaker and stakeholder concerns, ASHP recognizes the important intent and role of the 340B program and stresses the need for its continued sustainability. These developments demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment.

The original intent of the 340B program was to "to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rept. 102-384, pt. 2, at 12 [1992]). ASHP believes that the program should expand in alignment with its intent, which may or may not include use in the inpatient setting. ASHP emphasizes the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. Further, there is a need for communication and collaboration with state Medicaid programs to ensure optimization of benefits from the 340B program and Medicaid reimbursement policies. Because manufacturers must offer 340B discounts to covered entities to have their drugs covered by Medicaid, Medicaid policies will impact organizations with a 340B program. These impacts include but aren't limited to disproportionate share adjustment percentages, outpatient drug reimbursement policies, and drug rebate programs (i.e., whether a covered entity is "carved in" or "carved out").

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to recommend amending ASHP policy 1407, 340B Drug Pricing Program Sustainability, as follows (<u>underline</u> indicates new text):

> To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,
>
> To advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,
>
> <u>To advocate with state Medicaid programs to ensure that reimbursement policies promote 340B program stability; further,</u>

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; further,

To encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

In making its recommendation, the Advisory Panel discussed the need for communication and collaboration with state Medicaid programs in order to ensure equal benefit exists with 340B covered entities and Medicaid reimbursement policies. Given that manufacturers must offer 340B discounts to covered entities to have their drugs covered by Medicaid, Medicaid policies will impact organizations with a 340B program. This includes but isn't limited to disproportionate share adjustment percentages, outpatient drug reimbursement policies, and drug rebate programs (i.e., whether a covered entity is "carved in" or "carved out").

6. Federal Review of Anticompetitive Practices and Price Increases by Drug Product Manufacturers

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

To encourage appropriate federal review of these practices; further,

To advocate that drug product manufacturers be required to provide public notification in advance of significant price increases.

(Note: This policy would supersede ASHP policy 0814.)

Rationale

A healthy market for drug products increases patient access to drugs and lowers drug costs. ASHP recognizes several threats to the health of that market and advocates legislative, regulatory, and oversight solutions, including 1) reducing drug monopolies by incentivizing competition for additional generic drug market entrants, 2) targeting exclusivity protections to truly innovative products, and 3) appropriate federal review of anticompetitive practices by drug product manufacturers. ASHP 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. Payments to delay generic entry should be reviewed by the Federal Trade Commission because of their potentially anticompetitive nature and their possible violation of antitrust laws. ASHP also 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 sometimes abused to extend market exclusivity. Another solution advocated by ASHP is curbing misuse of REMS, which are sometimes 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. In addition to such a report, ASHP advocates that drug product manufacturers be required to provide public notification in advance of significant price increases.

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to amend ASHP policy 0814, Federal Review of Anticompetitive Practices by Drug Product Manufacturers, as follows (<u>underline</u> indicates new text):

> To strongly oppose anticompetitive practices by manufacturers that adversely affect drug product availability and price; further,
>
> To encourage appropriate federal review of these practices<u>; further,</u>
>
> <u>To advocate that manufacturers be required to provide public notification in advance of significant price increases.</u>

In making its recommendation, the Advisory Panel suggested amending this policy due to recent drug price increases. Requiring early notification would enable health systems to proactively manage shortages and their budgets. The Panel was sensitive to the question of whether this would be anticompetitive in cases where there is a sole-source product and advised the Council to have further discussion related to this question. The Council agreed with

the suggested Advisory Panel's edits to the policy but recognized that defining terms like "significant" would be difficult. The Council was not as concerned over the issue of public notification on a sole-source product provided that proprietary contractual information among supply chain members would not be revealed.

7. Federal Quality Rating Program for Pharmaceutical Manufacturers

To advocate that the Food and Drug Administration (FDA) assign quality ratings to pharmaceutical manufacturers based on the quality of their manufacturing processes, sourcing of active pharmaceutical ingredients and excipients, selection of contract manufacturers, and business continuity plans; further,

To advocate that the FDA consider offering incentives for manufacturers to participate in the program.

Rationale

Shortages of critical drug products in hospitals and health systems continue to pose a significant threat to public health, and pharmacists and other clinicians are often challenged with locating supplies of life-saving or life-sustaining drug products at a moment's notice and with very few options to choose from. While the number of new shortages has fallen considerably since 2011, a number of drug products remain in short supply. Drug product shortages are often caused by a manufacturing problem (e.g., contamination) that halts production until the problem is resolved. To address the issue of quality in drug product manufacturing, the FDA has considered creation of a manufacturing quality initiative that would highlight companies that employ the best quality manufacturing processes by establishing a rating system that would assign a rating to companies based on their level of quality in the manufacturing process. This rating system could be made public to enable prospective customers to see which companies employ the best quality practices. Further, the rating system could serve as a basis for FDA to offer incentives to companies who consistently rate higher than competitors.

Background

Based upon a recent drug product shortages meeting among clinician groups, the FDA, American Hospital Association, and the Department of Health and Human Services, the Council brought forth new policy that would support the creation of a quality ratings program for drug manufacturers as a way to help prevent and mitigate drug product shortages. The plan would consist of FDA-applied ratings for drug manufacturers based on their manufacturing processes, with a specific focus on quality. The companies that demonstrate higher levels of manufacturing quality would receive higher ratings, resulting in more public confidence in that manufacturer's ability to make products.

8. Intravenous Fluid Manufacturing Facilities as Critical Public Health Infrastructure

To advocate that federal and state governments recognize intravenous fluid manufacturing facilities as critical public health infrastructure.

Rationale

In the wake of hurricane Maria's impact on Puerto Rico in 2017, there has been rising interest in examining drug shortages from a national security perspective. The vulnerability of drug manufacturing on the island of Puerto Rico underscored a need to more closely evaluate the potential impacts of natural disasters on drug manufacturing and the production of critical pharmaceutical supplies. The Department of Homeland Security's list of key infrastructure includes public health infrastructure. ASHP advocates that public health infrastructure be defined to include manufacturing sites of intravenous fluids and that those sites be afforded the same protections as other critical infrastructure. Such protections should include an evaluation of manufacturing vulnerabilities such as geographic location, vulnerability of surrounding infrastructure such as roads or ports, and whether the company has developed business continuity plans or redundancies in manufacturing. Entities deemed critical public health infrastructure should be required to make necessary changes to ensure that manufacturing is not at risk for a supply disruption.

Background

The Council discussed the impacts of hurricane Maria on pharmaceutical manufacturing in Puerto Rico, notably on small-volume parenteral solutions. Given the severe shortages following the hurricane, the Council noted increased interest in examining drug shortages from a national security perspective. The Council concluded that one approach would be to advocate that the Department of Homeland Security designate intravenous fluid manufacturing facilities as public health infrastructure. The Council believes that such public health infrastructure should include manufacturing sites of intravenous fluids and should therefore be evaluated by risk of natural disasters or other risks to manufacturing capacity. Depending on the risk factors, manufacturers could be encouraged to establish backup plans in the event of a disaster.

9. Medical Devices

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

(Note: This policy would supersede ASHP policy 9106.)

Rationale

The lines between devices, drugs, and technology are blurring as new and innovative technologies combine drugs and devices. Because drugs and medical devices undergo different approval processes, it is important that compatibility between the intended use of any device and the drugs to be used with that device be ensured during the approval process so that unintended and possibly detrimental consequences do not occur. In addition, clinicians require information about the intended use of devices in all phases of the medication-use process in order to make the best-informed decisions about patient care.

Background

The Council reviewed ASHP policy 9106, Medical Devices, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Council did not agree with the Panel's recommendation to discontinue the policy, noting the importance of the policy and the gap in policy regarding transparency and technology that would be created. The Council voted to recommend amending policy 9106 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> ~~To support public and private initiatives to clarify and define the relationship among drugs, devices, and new technologies in order to promote safety and effectiveness as well as better delivery of patient care.~~
>
> To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,
>
> To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

The Council reviewed the recommendations of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel to discontinue this policy. The recommendation was based on existing ASHP policies (e.g., 1020, Role of Pharmacists in Safe Technology Implementation; 1313, Drug-Containing Devices; 1302, Interoperability of Patient Care Technologies) that the Panel believed covers the intent of the policy 9106. The Council discussed the issue at length and ultimately decided that those policies would not be sufficient to cover the issue in policy 9106. The Council further decided that an update to the policy language would be more appropriate rather than discontinuation.

10. ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems

1 To discontinue the ASHP Statement on Principles for Including Medications and
2 Pharmaceutical Care in Health Care Systems (Appendix B).

Background
The Council reviewed the statement and agreed with the recommendation by the Formulary Review Panel that the statement was redundant with other ASHP policy positions. The Panel and Council noted that the statement was originally developed to address advocacy needs during Clinton-era healthcare reform efforts and that its content came directly from ASHP policy positions. Although the Panel and Council recognized the value of a policy statement on healthcare reform, it was agreed that in such a rapidly changing policy landscape that ASHP policy positions are a more appropriate method for adopting and adapting policy to member needs. The Council also noted that ASHP had recently created the Board-approved ASHP Principles on Healthcare Reform successfully using the approach of collecting ASHP policy positions on the topic.

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.)

- Regulation of Automated Drug Dispensing Systems (9813)
- Licensure for Pharmacy Graduates of Foreign Schools (0323)
- Education, Prevention, and Enforcement Concerning Workplace Violence (0810)
- Regulation of Dietary Supplements (0811)
- Appropriate Staffing Levels (0812)
- Public Funding for Pharmacy Residency Training (0325)
- Pharmacists' Role in Immunization (1309)
- Regulation of Telepharmacy Services (1310)
- Regulation of Centralized Order Fulfillment (1311)

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has

created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Government Negotiation of Drug Prices

The sharp increase in drug prices jeopardizes patient access to drugs and places a severe strain on the healthcare system. High drug costs can impact patient outcomes by decreasing patient adherence due to financial burdens. Increased drug prices also place enormous budgetary pressure on healthcare organizations.

The Council discussed potential new policy on government negotiation of drug pricing in response to a recommendation from the June 2017 House of Delegates. Given both the controversial nature of this recommendation and the potential for unintended consequences, the Council decided that new policy was not appropriate at this time. However, the Council is recommending that ASHP sections and section advisory groups conduct additional research and discussion that could guide future policy.

The Council suggested that another option could be to develop a simple statement for the Board of Directors that expresses concerns over high drug prices, and exploring the possibility of developing a more in-depth statement at a later date that includes research, analysis, and policy recommendations.

Pharmacy Benefit Management (PBM) Transparency Regarding Direct and Indirect Remuneration (DIR) Fees

The Council discussed potential elements of a policy recommendation on the topic given that it has significant financial impact on health systems. While there was widespread agreement over the necessity of such a policy on DIR fees, Council members wondered whether the policy should be expanded to include more transparency over PBM rebates given by manufacturers and how that impacts pharmaceutical pricing. Mr. Hill volunteered to check with the Council on Pharmacy Management to determine the scope of their related agenda item for Policy Week, and Drs. Lee and Fox volunteered to work with Dr. Guharoy on drafting potential policy language for Policy Week.

Proposed Resolution on Specialty Drug Products

At its second June meeting, the House of Delegates voted to refer a resolution on FDA Criteria for Specialty Drug Products Available through Restricted Drug Distribution for further study by the Council on Public Policy. It was the consensus of the Council that empowering the FDA to define specialty drug products would not be advisable. The Council expressed concern that an FDA definition could invite abuse by manufacturers. If FDA develops criteria defining a specialty

drug, drug manufacturers could make their products fit the specified criteria, creating more specialty drugs and restricted distribution channels. The Council discussed whether a broadly agreed-upon definition would be helpful and what ASHP's role in developing such a definition should be. Although the Council generally supported the resolution's intent, the Council agreed with the Board of Directors that ASHP policy 1714, Restricted Drug Distribution, was a better means to achieve the outcome sought in the resolution, particularly that patient safety should be the sole criterion for determining whether restricted distribution is necessary.

Appendix A. ASHP Statement on Advocacy as a Professional Obligation

Position

ASHP believes that all pharmacists have a professional obligation to advocate on behalf of patients and the profession. Pharmacists should stay informed of issues that affect medication-related outcomes and advocate on behalf of patients, the profession, and the public. These issues may include legal, regulatory, financial, and other health policy issues, and this obligation extends beyond the individual practice site to their broader communities. ASHP recognizes that to fulfill this obligation, training and education is needed. ASHP urges all pharmacists to accept this responsibility and to be advocates both within and outside the profession, in the community, and in society as a whole to strengthen the care of our patients.

Role of Professional Organizations in Promoting Advocacy

Advocacy can be defined as an activity by an individual or group to plead a case, support a cause, or to recommend a course of action related to political, economic, social, institutional or patient-care issues. When attempting to define the advocacy responsibilities for pharmacy, it is instructive to examine the guidance from other healthcare professional organizations regarding advocacy.

One role professional organizations play is to help define the moral and ethical responsibilities of the profession. The American Medical Association (AMA) and the American Nurses Association (ANA) articulate how the members of those professions should be involved in advocacy efforts. The *AMA Code of Medical Ethics* states that "physicians, individually and collectively through their professional organizations and institutions, should participate in the political process as advocates for patients (or support those who do) so as to diminish financial obstacles to access health care" and that "the medical profession must work to ensure that societal decisions about the distribution of health resources safeguard the interests of all patients and promote access to health services."[1] These statements emphasize several responsibilities for the physician outside care for individual patients. Physicians are explicitly urged to participate in the political process as advocates and to make sure societal decisions are in the interest of all patients. Simply providing excellent patient care to patients within the physician's practice is not enough to meet the physician's ethical obligations.

The ANA *Code of Ethics with Interpretive Statements* Provision 8 states that "[t]he nurse collaborates with other health professionals and the public to protect human rights, promote health diplomacy, and reduce health disparities," which is further elaborated in Interpretive Statement 8.2 to mean that "[n]urses must lead collaborative partnerships to develop effective public health legislation, policies, projects and programs that promote and restore health, prevent illness, and alleviate suffering."[2] Provision 9 emphasizes the important role of nursing professional organizations in advocacy: "The profession of nursing, collectively through its professional organizations, must … integrate principles of social justice into nursing and health policy."[2] One prominent nurse advocate has described advocacy as "the cornerstone of nursing – nurses advocate for patients, causes, and the profession. Our advocacy, motivated by moral and ethical principles, seeks to influence policies by pleading or arguing within political, economic, and social systems, and also institutions, for an idea or cause that can lead to decisions in resource allocation that promote nurses, nursing, and all of healthcare."[3]

Advocacy as a Professional Obligation

Current ASHP policies encourage pharmacists to serve as advocates for their patients and the profession. For example, ASHP Policy 1114, Pharmacist Accountability for Patient Outcomes, states in part that ASHP and pharmacists should "promote pharmacist accountability as a fundamental component of pharmacy practice to other healthcare professionals, standards-setting and regulatory organizations, and patients."[4] The ASHP Statement on Leadership as a Professional Obligation notes that "the practice of effectively influencing the behavior of physicians, nurses, pharmacy technicians, interns, support staff, and others to optimize medication safety and patient outcomes constitutes successful leadership."[5] ASHP policy position 1501, Pharmacist Participation in Health Policy Development, clearly articulates the role pharmacists should play in developing health policy: "To advocate that pharmacists participate with policymakers and stakeholders in the development of health-related policies at the national, state, and community levels…."[4] The ASHP Statement on the Role of Health-System Pharmacists in Public Health states that "health-system pharmacists should be involved in public health policy decision-making and in the planning, development, and implementation of public health efforts. Health-system pharmacists can improve public health by … advocating for sound legislation, regulations, and public policy regarding disease prevention and management; and engaging in public health research."[6]

ASHP not only encourages pharmacists to participate in advocacy efforts but believes that pharmacists have a professional and moral obligation to do so. That obligation stems from the covenantal relationship between the pharmacist and their communities described in the profession's shared *Code of Ethics of the Pharmacist* and the *Oath of a Pharmacist*. The *Code of Ethics of a Pharmacist* states that "[a] pharmacist serves individual, community, and societal needs" and "seeks justice in the distribution of health resources."[7] While the Code makes clear that the primary obligation of a pharmacist is to individual patients, the pharmacist's responsibility extends at times beyond the individual to the community and society. The specific instance provided in the language of the Code is the distribution of health resources, in which pharmacists are called upon to seek a just distribution. The *Oath of a Pharmacist*, which college of pharmacy graduates across the country swear to, reads in part:

- I will consider the welfare of humanity and relief of suffering my primary concerns.
- I will embrace and advocate changes that improve patient care.[8]

The pharmacist's advocacy responsibilities are also evident in ASHP Vision and Mission statements. The ASHP Vision is "that medication use will be optimal, safe, and effective for all people all of the time," and the ASHP Mission states in part that "ASHP serves its members as their collective voice on issues related to medication use and public health."[9] The broad purview of these statements is reinforced by the ASHP Statement on Professionalism, which implores pharmacists to "commit themselves to improving healthcare institutions not simply for the well-being of individual patients but for the benefit of society as a whole" and "to join forces with other healthcare providers and patients … to attain the kind of healthcare system our patients deserve and our society demands."[10]

These professionwide and ASHP policies, like those of our professional counterparts in medicine and nursing, are a clear statement of the professional obligation members of the

profession have to involve themselves in the policy-making process to advocate for the needs of patients, the profession, and the public, both within and outside healthcare settings.

Preparing Pharmacist Advocates

Pharmacy education at several different levels includes recommendations that learners develop advocacy skills. The Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)* include the following learning expectations for professional communications and public health, respectively:

- Analysis and practice of verbal, non-verbal, and written communication strategies that promote effective interpersonal dialog and understanding to advance specific patient care, education, advocacy, and/or interprofessional collaboration goals.
- Exploration of population health management strategies, national and community-based public health programs, and implementation of activities that advance public health and wellness.[11]

These expectations demonstrate that pharmacy students will be taught strategies to be successful advocates for a range of topics, including population health management strategies. This approach to teaching pharmacy students about population health strategies and other means of advancing public health suggests that pharmacists, as well as students, should begin to think not just about their obligations to individual patients but also to use their training to impact the health of communities or society as a whole. There is a push for more of this type of training for pharmacy students. In 2016, the American Association of Colleges of Pharmacy (AACP) published Public Health and the CAPE 2013 Educational Outcomes: Inclusion, Pedagogical Considerations and Assessment, which provides guidance to the pharmacy profession on methods to use the Center for the Advancement of Pharmacy Education (CAPE) 2013 outcomes to incorporate public health within college of pharmacy curricula and in co-curricular programs/activities and delineates public health-related course objectives for both didactic and experiential courses. Two of the paper's recommended competency areas for integration of public health into didactic Pharm.D. curricula are:

- Process of health policy-making (e.g., local, state, federal government).
- Methods for participation in the policy process (e.g., advocacy, advisory processes, opportunities and strategies to impact policy and public health problems).[12]

Pharmacy residency training also incorporates advocacy. The Required Competency Areas, Goals, and Objectives for Postgraduate Year One (PGY1) Pharmacy Residencies states that one of the criteria for demonstrating "personal, interpersonal, and teamwork skills critical for effective leadership" is that a resident "effectively expresses benefits of personal profession-wide leadership and advocacy."[13]

Conclusion

ASHP believes pharmacists have a moral and ethical professional obligation to advocate for "changes that improve patient care"[8] as well as "justice in the distribution of health resources."[7] Specific ASHP policies on various aspects of healthcare, population health, and

public health stem from this general obligation. To meet this professional obligation, pharmacist advocates will need appropriate training and education.

References

1. American Medical Association [AMA]. AMA Code of Medical Ethics Opinion 11.1.4 (b) & (c). https://www.ama-assn.org/delivering-care/financial-barriers-health-care-access (accessed 2017 Nov 28).
2. American Nurses Association [ANA]. ANA Code of Ethics with Interpretive Statements. http://nursingworld.org/DocumentVault/Ethics-1/Code-of-Ethics-for-Nurses.html (accessed 2017 Nov 28).
3. Matthews J. Role of professional organizations in advocating for the nursing profession. *OJIN* 17; 2012: Manuscript 3. DOI: 10.3912/OJIN.Vol17No01Man03 http://nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-17-2012/No1-Jan-2012/Professional-Organizations-and-Advocating.html (accessed 2017 Nov 28).
4. American Society of Health-System Pharmacists [ASHP]. ASHP policy position 1501, Pharmacist Participation in Health Policy Development. In: ASHP Policy Positions 1982-2017. https://www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines/Browse-by-Document-Type/Policy-Positions (accessed 2017 Nov 28).
5. American Society of Health-System Pharmacists [ASHP]. ASHP Statement on Leadership as a Professional Obligation. www.ashp.org/-/media/assets/policy-guidelines/docs/statements-leadership-as-professional-obligation.ashx (accessed 2017 Nov 28).
6. American Society of Health-System Pharmacists [ASHP]. ASHP Statement on the Role of Health-System Pharmacists in Public Health. https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/role-of-health-system-pharmacists-in-public-health.ashx (accessed 2017 Nov 28).
7. American Pharmacists Association. Code of Ethics for Pharmacists. https://www.ashp.org/-/media/assets/policy-guidelines/docs/code-of-ethics-for-pharmacists.ashx (accessed 2017 Nov 28).
8. American Pharmacists Association. Oath of a Pharmacist. http://www.pharmacist.com/oath-pharmacist (accessed 2017 Nov 28).
9. American Society of Health-System Pharmacists [ASHP]. About ASHP. https://www.ashp.org/About-ASHP (accessed 2017 Nov 28).
10. American Society of Health-System Pharmacists [ASHP]. ASHP Statement on Professionalism. https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/professionalism.ashx (accessed 2017 Nov 28).
11. Accreditation Council for Pharmacy Education. Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016) https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf (accessed 2017 Nov 28).
12. Public Health and the CAPE 2013 Educational Outcomes: Inclusion, Pedagogical Considerations and Assessment. http://www.aacp.org/governance/councilfaculties/Documents/PublicHealthSIGCAPEpaper.pdf (accessed 2017 Nov 28).
13. American Society of Health-System Pharmacists. Required Competency Areas, Goals, and Objectives for Postgraduate Year One (PGY1) Pharmacy Residencies. www.ashp.org/-/media/assets/professional-development/residencies/docs/required-competency-areas-goals-objectives (accessed 2017 Nov 28).

Appendix B. ASHP Statement on Principles for Including Medications and Pharmaceutical Care in Health Care Systems

Introduction

The United States government, individual state governments, and private health care systems are moving toward reforming the way that they provide health care to their citizens or beneficiaries. As they do so, policy makers must improve their medication-use systems to address problems of access, quality, and cost of medicines and pharmaceutical care services. This document offers principles for achieving maximum value from the services of the nation's pharmacists.

Although pharmaceuticals and pharmaceutical care are among the most cost-effective methods of health care available, there is evidence that the public is not currently realizing the full potential benefit from these resources. Illnesses related to improper medication use are costing the health care systems in the United States billions of dollars per year in patient morbidity and mortality. Pharmacists are prepared and eager to help other health providers and patients prevent and resolve medication-related problems, and health care systems should facilitate and take advantage of pharmacists' expertise.

These principles are offered to guide health policy makers in their deliberations concerning the inclusion of medications and pharmacists' services in health care systems.

Principles

Principle I. Health care systems must make medications available to patients and provide for pharmaceutical care, which encompasses pharmacists' health care services and health promotional activities that ensure that medications are used safely, effectively, and efficiently for optimal patient outcomes.

Principle II. Careful distinction must be made between policies that affect pharmacist reimbursement and policies that affect pharmacist compensation. Health care systems must reimburse pharmacists for the medications they provide patients (including the costs of drug products, the costs associated with dispensing, and related administrative costs). Health care systems also must compensate pharmacists for the services and care that they provide to patients, which result in improved medication use and which may not necessarily be associated with dispensing.

Principle III. Patients differ in their needs for pharmaceutical care services. The method of compensating pharmacists for their services must recognize the value of the different levels and types of services that pharmacists provide to patients based on pharmacists' professional assessments of patients' needs.

Principle IV. Pharmacists must be enabled and encouraged to use their professional expertise in making medication related judgments in collaboration with patients and health care colleagues. Health care systems must not erect barriers to pharmacists' exercising professional judgments; nor should health care systems prescribe specific services or therapies for defined types of patients.

Principle V. Pharmacists should have access to relevant patient information to support their professional judgments and activities. Pharmacists should be encouraged and permitted

to make additions to medical records for the purpose of adding their findings, conclusions, and recommendations. Pharmacists will respect the confidential nature of all patient information.

Principle VI. Health care systems must be designed to enable, foster, and facilitate communication and collaboration among pharmacists and other care providers to ensure proper coordination of patients' medication therapies.

Principle VII. Quality assessment and assurance programs related to individual patient care should be implemented at local levels through collaborative efforts of health care practitioners rather than through centralized bureaucracies. Quality assessment and assurance procedures for medication use (such as pharmacy and therapeutics committees, formulary systems, drug-use evaluation programs, and patient outcomes analyses) are most effective when the professionals who care for covered patients are involved in the design and implementation of the procedures. Moreover, such programs must recognize local variations in epidemiology, demography, and practice standards. Information related to quality assessment and assurance activities must be held in confidence by all parties.

Principle VIII. Demonstration projects and evaluation studies in the delivery of pharmaceutical care must be enabled, fostered, and implemented. New services, quality assessment and assurance techniques, and innovative medication delivery systems are needed to improve the access to and quality of medication therapy and pharmaceutical care while containing costs.

Principle IX. Health care policies that are intended to influence practices of those associated with pharmacy, such as the pharmaceutical industry or prescribers, should address those audiences directly rather than through policies that affect reimbursement, compensation, or other activities of pharmacists.

This statement was reviewed in 2012 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Approved by the ASHP Board of Directors, November 18, 1992, and by the ASHP House of Delegates, June 7, 1993. Developed by a committee of the Joint Commission of Pharmacy Practitioners and subsequently reviewed and approved by the ASHP Council on Legal and Public Affairs.

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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.

Stephen F. Eckel, *Board Liaison*

1. Ensuring Effectiveness, Safety, and Access to Orphan Drug Products

To encourage continued research on and development of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of these drug products for approved and off-label indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products; further,

To urge federal review to evaluate whether orphan drug status is being used inappropriately to extend patents and decrease competition, reducing patient access.

(Note: This policy would supersede ASHP policy 1413.)

Rationale

The U.S. Orphan Drug Act of 1983 and similar programs in other countries have greatly expanded the number of therapies available to treat rare diseases through the use of financial and other incentives that encourage drug manufacturers to develop medications for limited

patient populations. Despite the overall success of orphan drug programs, concerns have been raised about the breadth of drugs approved through these mechanisms. Although there are more than 7,000 designated orphan diseases in the United States, oncology drugs represent approximately 33 percent of all orphan drug approvals. ASHP believes that there is a significant need to develop a more comprehensive approach to orphan drug development in order to encourage drug manufacturers to expand the breadth of rare conditions treated by these therapies.

Once an orphan drug is approved, it may be used without restrictions, and these therapies are frequently used to treat patients and conditions that were not assessed during pre-approval clinical studies. While this use can spur innovation and lead to advances in the treatment of common diseases, ASHP believes that this use is also associated with the potential for increased patient harm, given the small patient populations and other characteristics common to studies used to support orphan drug approval. Research is necessary to evaluate the safety and effectiveness of these therapies under real-use conditions. In addition to manufacturer-conducted research, ASHP encourages private and public sector research in order to provide sufficient evidence to support off-label use.

ASHP is concerned about the high cost of these therapies, which contributes to increased healthcare costs and potentially decreases patient access, especially among those who are under- or uninsured. Further, some orphan drugs have later been discontinued by the drug manufacturer—an occurrence that often leaves patients with rare conditions without a treatment alternative. It is essential that stakeholders (e.g., health policymakers, payers, and pharmaceutical manufacturers) continue efforts to provide patient access to these therapies, including developing strategies to ensure that the cost of these therapies does not create an unreasonable barrier to patient access.

There are additional challenges regarding patient access to orphan drugs. There is a need for more emphasis on increasing patient access and addressing 340B issues, especially with critical access facilities. Orphan drug development and marketing in the U.S. is concentrated in a few therapeutic areas. Despite the increase in the number of orphan drugs approved by the Food and Drug Administration, the unmet needs of patients with rare diseases provide evidence that the current incentives are not efficiently stimulating orphan drug development. There is need to balance economic incentives to stimulate the development and marketing of orphan drugs without jeopardizing patients' access to treatment.

Background

The Council reviewed ASHP policy 1413, Ensuring Effectiveness, Safety, and Access to Orphan Drug Products, on the recommendation of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel and voted to recommend amending the policy as follows (underscore indicates new text):

> To encourage continued research on and development of orphan drug products; further,
>
> To advocate for the use of innovative strategies and incentives to expand the breadth of

rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of these drug products for approved and off-label indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products; further,

To urge federal review to evaluate whether orphan drug status is being used inappropriately to extend patents and decrease competition, reducing patient access.

The Council concurred with the Panel's concerns and supported the language addition to policy 1413 and added to the rationale to support the updated clause.

In addition, the Council also discussed a requested amendment to ASHP policy 1413 from the House of Delegate to include a clause that advocates being more inclusive of educating pharmacists and other healthcare providers about rare (orphan) diseases. The Council acknowledged that many healthcare providers may not be familiar with rare diseases but that ASHP could meet this need through its various educational avenues.

2. Rational Use of Medications

To recognize that irrational medication use is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To support and promote evidenced-based prescribing for indication, efficacy, safety, duration, cost, and suitability for the patient; further,

To advocate that pharmacists lead interprofessional efforts to promote the rational use of medications, including engaging in strategies to monitor, detect, and address patterns of irrational medication use in patient populations.

(Note: This policy would supersede ASHP policy 1312.)

Rationale

The World Health Organization (WHO) identifies that rational use of medications requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." The overuse, underuse, or misuse of medicines results in wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include use of too many medicines per patient, inappropriate use of antimicrobials, inadequate dosage, overuse of injections when oral formulations would be more appropriate, failure to prescribe in accordance with clinical guidelines, inappropriate self-medication, decreased access to medicines, and nonadherence to dosing regimens. These actions can negatively affect the

quality of patient care, raise healthcare costs, and increase the number of adverse reactions and events, and may cause adverse reactions or negative psychosocial effects.

Strategies to address irrational medication use can be characterized as educational, managerial, economic, or regulatory in nature. Furthermore, the WHO advocates 12 key interventions to promote more rational use of medications:

- establishment of a multidisciplinary national body to coordinate policies on medication use;
- use of clinical guidelines;
- development and use of national essential medications list;
- establishment of drug and therapeutics committees in districts and hospitals;
- inclusion of problem-based pharmacotherapy training in undergraduate curricula;
- continuing in-service medical education as a licensure requirement;
- supervision, audit, and feedback;
- use of independent information on medications;
- public education about medications;
- avoidance of perverse financial incentives;
- use of appropriate and enforced regulation; and
- sufficient government expenditure to ensure availability of medications and staff.

These recommendations are echoed by the Joint Commission of Pharmacy Practitioners, whose tenets of the pharmacists' patient care process include the collection of necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient; assessment of information collected and analysis of the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care; development of an individualized patient-centered care plan, in collaboration with other healthcare professionals and the patient or caregiver that is evidence-based and cost-effective; implementation of the care plan in collaboration with other healthcare professionals and the patient or caregiver; and monitoring and evaluation of the effectiveness of the care plan and modification of the plan in collaboration with other healthcare professionals and the patient or caregiver as needed.

Background

The Council discussed this topic as a part of the sunset review of ASHP policy 1312, Medication Overuse, which reads:

> To define medication overuse as use of a medication when the potential risks of using the drug outweigh the potential benefits for the patient; further,
>
> To recognize that medication overuse is inappropriate and can result in patient harm and increased overall healthcare costs; further,
>
> To advocate that pharmacists take a leadership role in interprofessional efforts to

minimize medication overuse.

The Council recognized that there are significant costs, adverse effects, and safety events related not only to medication overuse but also underuse, misuse, and omission. The WHO-recommended key interventions touched upon many of the topics brought up by the Council and already align with common areas where pharmacists or pharmacy departments are already participants. The Council suggested discontinuing policy 1312 and replacing it with the recommended policy language.

3. Responsible Medication-related Clinical Testing and Monitoring

To recognize that overuse of clinical testing is an increasingly recognized problem in practice that can lead to unnecessary costs, waste, and patient harm; further,

To encourage pharmacists to engage in interprofessional efforts to promote the appropriate but judicious use of testing, monitoring, assessment of clinical progress, dose adjustment, and discontinuation of medication therapy, where appropriate; further,

To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate use of procedures and test ordering in healthcare systems.

Rationale

As the prevalence of collaborative practice grows and as pharmacist care expands into direct patient care services, so too do the responsibilities held by these practitioners. In many institutions, pharmacists' responsibilities now include ordering blood draws as a part of initiating a medication regimen, assessing drug levels, monitoring for adverse effects, or ordering imaging such as ultrasound for evaluating a deep vein thrombosis or an electrocardiogram to evaluate a QTc interval.

Overuse of medical care is a long-recognized problem in clinical medicine, and more spending and treatment do not translate into better patient outcomes and health. The number of articles on overuse nearly doubled from 2014 to 2015, indicating that awareness of overuse is increasing, despite little evidence of improved practice, which may mean that the overuse of diagnostic tests and lab monitoring is leading to patient harm and could outweigh benefits. Healthcare continues to be enthralled by high-technology innovation, including both therapies and tests. Once practice norms are established, clinicians are slow to de-implement services, even those that are found to be potentially dangerous. Reasons for excessive ordering of tests by healthcare providers include defensive behavior, fear, uncertainty, lack of experience, the use of protocols and guidelines, routine clinical practice, inadequate educational feedback, and clinician's lack of awareness about the cost of examinations. Inappropriate testing causes unnecessary patient discomfort, entails the risk of generating false-positive results, leads to

overloading of diagnostic services, wastes valuable healthcare resources, and is associated with other inefficiencies in healthcare delivery, undermining the quality of health services.

Choosing Wisely is a national program designed to help raise provider and public awareness and garner support for appropriate test utilization, with the goal of promoting conversations between providers and patients about choosing appropriate care in order to reduce both harm and waste. In 2016, ASHP announced its partnership with the ABIM Foundation on the Choosing Wisely campaign and is the first pharmacy organization to participate in the campaign.

Background

The Council discussed this topic as a part of the sunset review of ASHP policy 1312, Medication Overuse. Many Council members have some level of ability to order labs and other procedures for diagnosis, monitoring, and guidance of medication therapy. Council members also shared experiences where lab draws were unnecessary, caused patient harm, and contributed to waste.

4. Clinical Practice and Application on the Use of Biomarkers

To promote appropriate, evidence-based use of biomarkers in clinical practice; further,

To encourage research that evaluates the clinical and safety implications of biomarkers in the care of patients and to guide clinical practice; further,

To promote Food and Drug Administration (FDA) approved qualified medication biomarkers in drug development, regulation, and use in clinical practice; further,

To foster the development of timely and readily available resources about biomarkers and their evidenced based application in practices.

Rationale

The National Institutes of Health Biomarkers Definitions Working Group defined a biomarker as "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention." In comparison to a clinical endpoint, a biomarker is strictly objective and quantifiable, whereas a clinical endpoint reflects the subject's well-being and health status from the subject's perspective. As defined by the FDA, a biomarker is "a defined characteristic that is measured as an indicator of normal biological processes, or responses to an exposure or intervention, including therapeutic interventions." The FDA classifies biomarkers in the following categories: susceptibility/risk biomarker, diagnostic biomarker, monitoring biomarker, prognostic biomarker, predictive biomarker, pharmacodynamic/response biomarker, and safety biomarker.

Further, the FDA and Center for Drug Evaluation and Research are involved in regulating biomarkers in drug development, regulation, and use in clinical practice. Under the FDA Biomarker Qualification Program, researchers can request qualification of a biomarker in the use of drug development. The FDA's involvement in biomarker qualifications allows for the development of a regulatory process to investigate the safety and efficacy of biomarkers. Innovative and newly discovered biomarkers are investigated or found unexpectedly in clinical research. Recently published articles demonstrate newly discovered biomarkers that potentially show clinical efficacy; however, there is debate about how to conduct further research to establish a biomarker's clinical efficacy.

This growth in discovery and application of established biomarkers in practice presents several practice issues, including use of recognized biomarkers, collaborating with practitioners concerning newly discovered or rising biomarkers, conducting research on the outcomes of the use of various biomarkers, and integrating use of biomarkers into practice.

Background

Practitioners are seeing more and more data published on using biomarkers in various areas of practice including utilization to in treatment protocols as well as dual roles in diagnostic and monitoring.

5. Medication Overuse

To discontinue ASHP policy 1312 Medication Overuse, which reads:

To define medication overuse as use of a medication when the potential risks of using the drug outweigh the potential benefits for the patient; further,

To recognize that medication overuse is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To advocate that pharmacists take a leadership role in interprofessional efforts to minimize medication overuse.

Background

The Council reviewed this policy as a part of sunset review and concluded that, although aspects of medication overuse still contribute to patient care aspects within practice, such as overuse of antimicrobials and opioids, there are other ASHP policies that address these contemporary issues (1702, Reduction of Unused Prescription Drug Products; 1722, Pain Management; 1614, Controlled Substance Diversion and Patient Access; 1603, Stewardship of Drugs With Potential for Abuse; 1604, Appropriate Use of Antipsychotic Drug Therapies; and the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control). Furthermore, the Council concluded that while overuse is

inappropriate and can cause patient harm, there are also significant issues with underuse and misuse of medications and medication classes as well, and that a more comprehensive policy (recommended above) that would supersede this policy is needed.

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.)

- Drug-Containing Devices (1313)
- DEA Scheduling of Controlled Substances (1315)

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

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

The Council reviewed the ASHP Therapeutic Position Statement on the Use of Antipsychotic Medications in the Treatment of Adults with Psychotic Disorders. The Council appreciated the expansion of the Therapeutic Position Statement from second generation antipsychotics to all classes of antipsychotics but could not approve the therapeutic position statement in its current draft. The Council is requesting clarification in specific areas of the document, including

the need to consider stroke prophylaxis in all elderly patients receiving antipsychotic drugs, particularly high-risk patients as this is not a practice members were familiar with; clarification on the pharmacogenomics aspects: use of QTc prolongation; and a request for a table in the document on the side of effects of these medications. The Council has provided in writing their questions and concerns for this document.

Antipsychotic Use in the Emergency Department (ED)

The Council discussed the care and medication issues that patients with psychiatric disease encounter in the ED and the challenges pharmacists face in treating this high-risk population. Given the lack of patient beds, extended period of time patients often spend in the ED, difficulty in assessing patients due to effects of medications that are sometimes needed to protect patients and staff, there is a definite need to help members with this area of practice. The Council acknowledged that the Section of Clinical Specialists and Scientists Section Advisory Group on Emergency Care is updating the ASHP Statement on Pharmacy Services to the Emergency Department and the ASHP Guidelines on Emergency Medicine Pharmacist Services and recommended that these revisions include considerations for psychiatric patients.

The Council also recognized that psychiatric patients are not only treated in the ED but also in outpatient and inpatient areas, and discussed the lack of pharmacists willing or able to precept students and residents in this practice area. Potential ways that ASHP could assist in meeting this need would be to develop a traineeship or certificate program; education through its various channels, including the Midyear Clinical Meeting; webinars; an article in *AJHP*; and possibly a web-based resource center.

Therapeutic Use of Probiotics

The Council discussed at length the difficulty of how to classify probiotics, as they are components of food items, dietary supplements, nutraceuticals, and other products in the marketplace and healthcare. The Council also addressed how these products and different strains are used in practice.

The Council determined that the majority of formulations and issues with pre- and probiotics did fall under existing ASHP policy and did not feel strongly enough that a separate policy is needed to address these issues. The Council did recommend that when the ASHP Statement on the Use of Dietary Supplements is updated, probiotics be included. Due to their variety, the Council recommended that ASHP provide education on the topic, as some strains have been studied and proven effective, through its various avenues of education, particularly an update to the March 15, 2010, *AJHP* article on probiotics, and a therapeutic debate topic at the Midyear Clinical Meeting. There was also interest in surveying the ASHP membership to discern how probiotics are being used so that ASHP can address member needs on this topic.

Biome Transfers

The Council reviewed the clinical aspects of biome transfers, including vaginal biome transfer and the more commonly used fecal matter transplant (FMT). With the success of FMT in the treatment of resistant *C. difficile* infections, there has been an expanding interest in the treatment of other diseases, including other gastrointestinal maladies, diabetes, obesity, neurologic disorders, and autism, with some or few studies on these emerging areas.

The Council felt that because FMT is an established treatment and has both therapeutic and practice elements that the Council on Pharmacy Practice should evaluate the need for a policy, as many of the topics discussed are outside the purview of the Council on Therapeutics. Operation logistics discussed included screening and management of donors, protocols including hazardous waste and biohazardous handling of fecal matter, storage and handling, and the role of the pharmacist. Council members who perform FMT at their institutions state that the pharmacy department does not have an integral role, as the transfer is done by a specialty service, such as the gastrointestinal specialist. The Council also recommended education through ASHP's various educational arms.

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

The Council discussed the ASHP Therapeutic Position Statement on the Use of Second-Generation Antipsychotic Medications in the Treatment of Adults with Schizophrenia and Schizoaffective Disorders (the TPS). The Council reviewed the recommended changes that were suggested upon their last review and noted typographical errors, nomenclature discrepancies, and referencing mistakes. The Council agreed that the information that was specific to antipsychotics appeared to be accurate and suggestions made from the last review were incorporated into the TPS. However, there was considerable concern with some of the cardiac and pharmacogenomic information in the TPS that requires change before the Council can approve it. The Council agreed to forward their comments to the authors for their review and consideration.

ASHP Therapeutic Position Statement on the Role of Pharmacotherapy in Preventing Venous Thromboembolism in Hospitalized Patients

The Council discussed the ASHP Therapeutic Position Statement on the Role of Pharmacotherapy in Preventing Venous Thromboembolism in Hospitalized Patients (the TPS). The Council agreed that the TPS no longer reflects current practice due to newer classes of drugs now available to treat this patient population. Upcoming and recently published trials with these new drugs classes will need to be incorporated into the statement, particularly in

the sections that address risk-assessment models, hip and knee replacement therapies, special populations, reversal, and extended duration therapy in the medically ill hospitalized patients. Despite these shortcomings, the guidelines still provide good advice on many areas of practice. The Council agreed that the TPS required revision and that ASHP staff would reach out to subject matter experts for updating.

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.

Linda S. Tyler, *Board Liaison*

Council Members

Nicole Clark, *Chair* (Massachusetts)
Whitney White, *Vice Chair* (Alabama)
David Gregory (Mississippi)
Seena Haines (Mississippi)
Tadd Hellwig (South Dakota)
Heather Jones, *New Practitioner* (Wisconsin)
Patricia Knowles (Georgia)
Krystal Moorman (Utah)
Marvin Ortiz, *Student* (California)
Kristine Parbuoni (California)
Rebecca Taylor (Ohio)
Lanita White (Arkansas)
Erika Thomas, *Secretary*

1. Clinician Well-being and Resilience

To acknowledge that the healthcare workforce encounters unique stressors throughout their education and careers that contribute to burnout; further,

To affirm that burnout adversely affects an individual's well-being and healthcare outcomes; further,

To encourage healthcare organizations to develop programs aimed at prevention, recognition, and treatment of burnout, and to support participation in these programs; further,

To encourage individual pharmacists to embrace resilience and well-being as a personal responsibility that should be supported by organizational culture; further,

To foster research on stress, burnout, and well-being, especially in pharmacy; further,

To collaborate with other professions to identify effective preventive and treatment strategies at an individual, organizational, and system level.

Rationale

Burnout is a syndrome characterized by a high degree of emotional exhaustion, high depersonalization (e.g., cynicism), and a low sense of personal accomplishment from work due to both internal and external factors. More than half of U.S. physicians show symptoms of burnout, which is nearly twice as high as other U.S. workers, even after controlling for work hours and other factors. Between 2011 and 2014, the prevalence of burnout increased by 9% among physicians while remaining stable in other U.S. workers. The American Foundation for Suicide Prevention reports that 300-400 physicians commit suicide each year, approximately one per day. Nurses show a similarly high prevalence of burnout and depression. A 2007 study reported that 22-35% of nurses had a high degree of emotional exhaustion. A survey at Duke University Hospital found that 20% of pharmacists were at risk for burnout. And although less is known about other members of the healthcare team, data suggest a similar prevalence of burnout among pharmacy technicians, nurse practitioners, and physician assistants.

Stress in our clinical learning environment can affect all healthcare learners, with negative outcomes ranging from poor well-being to substance abuse to depression, even suicide. Two New York City medical residents committed suicide in a 2-month period during the 2014–15 residency year. One review estimates that nearly 29% of medical residents suffer from depression or depressive symptoms, well above the 16% estimated prevalence in the general population. One study has shown that pharmacy residents exhibit high levels of perceived stress, especially those who work more than 60 hours per week, and perceived stress is highly correlated to negative effects.

ASHP joined the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience in 2017. The goals of the Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. Clinician burnout is a concern because, in addition to clinician suffering, clinician burnout has been associated with increased rates of medical errors, healthcare-associated infection, and patient mortality. Clinician burnout also decreases patient satisfaction and healthcare workforce productivity. Students in the health professions are also susceptible to burnout.

Studies suggest that burnout is a problem of the whole healthcare organization, rather than individuals, which indicates that pharmacists, along with other healthcare professionals and administrators, have a role in researching and solving the problem. To be successful, interventional programs must promote prevention, recognition, and treatment of burnout, and healthcare organizations must foster a culture that supports not just participation in these programs but a sense of personal responsibility for developing and maintaining resilience.

Providing patient care is meaningful and purposeful work. A healthcare organization with a resilient workforce will provide the best healthcare outcomes.

Background

The Council considered this topic as ASHP begins its participation in the National Academy of Medicine Action Collaborative on Clinician Well-Being and Resilience. Although ASHP has policy on pharmacists as second victims (ASHP policy 1524) and pharmacy fatigue (ASHP policy 0504), ASHP policy has not addressed the increasingly important issues of burnout, well-being, and

resilience directly. The recommended policy will promote ASHP efforts on these topics and support its work in the Action Collaborative.

2. Student Pharmacist Drug Testing

To advocate for the use of pre-enrollment, random, and for-cause drug testing throughout pharmacy education and prior to pharmacy practice experiences, based on defined criteria with appropriate testing validation procedures; further,

To encourage colleges of pharmacy to develop policies and processes to identify impaired individuals; further,

To encourage colleges of pharmacy to facilitate access to programs for treatment and recovery; further,

To encourage colleges of pharmacy to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

Rationale

Persons 18-25 years of age have the highest prevalence of prescription drug misuse among all age groups. Moreover, there is growing evidence that prescription drug misuse has been increasing among U.S. college students, and it is second to marijuana as the most common form of substance abuse. Pharmacy professionals and students are entrusted with the health, safety, and welfare of patients. They have access to controlled substances and confidential information, and operate in settings that require the exercise of good judgment and ethical behavior. Thus, an assessment of a student pharmacist's possible impairment, which could diminish his or her capacity to function in such a setting, is imperative to promote the highest level of integrity in healthcare services. ASHP recognizes that drug testing student pharmacists, whose responsibilities may bring them into contact with controlled substances, is an essential element of diversion prevention programs. Pre-enrollment, random, and 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 addiction recovery program, as outlined in the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance.

Background

The Council considered this topic at the suggestion of the ASHP Pharmacy Student Forum. In 2017, the House of Delegates approved ASHP policy 1717, Drug Testing, which reads:

> 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 Pharmacy Student Forum Executive Committee drafted the policy recommendation after recognizing the need for a policy to advocate for and encourage all colleges of pharmacy to employ drug testing prior to and throughout enrollment at the college.

3. Collaboration on Experiential Education

To encourage practitioner contributions to pharmacy education; further,

To encourage pharmacists and pharmacy leaders to recognize their professional responsibility to contribute to the development of new pharmacy practitioners; further,

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

To encourage colleges of pharmacy and health systems to define and develop collaborative organizational relationships that support patient care and advance the missions of both institutions in a mutually beneficial manner.

(Note: This policy would supersede ASHP policies 0315 and 0804.)

Rationale

As stated in the ASHP Statement on Professionalism, one of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission. Because the principles of institutional pharmacy practice are not emphasized in typical pharmacy curricula, professional socialization is especially important for pharmacists who practice in those settings. The experiential education experience of student pharmacists is a partnership between colleges of pharmacy and the experiential teaching sites. Collaboration between the colleges of pharmacy and experiential training sites on preceptor development, standardized rotation schedule dates, evaluation tools, and other materials helps to assure the best possible experience for student pharmacists, preceptors, and the experiential education site. In addition, collaboration allows both entities to fulfill their missions through mutually beneficial activities, improving patient outcomes, and helping students and their institutions achieve educational and research objectives.

Background

The Council reviewed ASHP policy 0804, Collaboration Regarding Experiential Education, and ASHP policy 0315, Practice Sites for Colleges of Pharmacy, as part of sunset review and voted to recommend amending policy 0804 as follows (underscore indicates new text):

> To encourage practitioner input in pharmacy education; further,
>
> To encourage pharmacists and pharmacy leaders to recognize their professional responsibility to contribute to the development of new pharmacy practitioners; further,
>
> To promote collaboration of experiential teaching sites with the colleges of pharmacy (nationally or regionally), for the purpose of fostering preceptor development, standardization of experiential rotation schedule dates and evaluation tools, and other related matters; further,
>
> To encourage colleges of pharmacy and health systems to define and develop collaborative organizational relationships that support patient care and advance the missions of both institutions in a mutually beneficial manner.

The Council combined the policies by adding much of the text of ASHP policy 0315, Practice Sites for Colleges of Pharmacy, which reads as follows:

> To encourage practitioner input in pharmacy education; further,
>
> To encourage that institutional and health-system environments be used as sites for experiential training of pharmacy students; further,
>
> To encourage colleges of pharmacy and health systems to define and develop appropriate organizational relationships that permit a balance of patient care and service, as well as educational and research objectives, in a mutually beneficial manner; further,
>
> To include the administrative interests of both the health system and the college of pharmacy in defining these organizational relationships to ensure compatibility of institutional (i.e., health system or university) and departmental (i.e., pharmacy department and department in the college) objectives; further,
>
> To encourage pharmacists and pharmacy leaders to recognize that part of their professional responsibility is the development of new pharmacy practitioners.

4. Promoting the Image of Pharmacists and Pharmacy Technicians

To promote the professional image of pharmacists and pharmacy technicians who work in acute and ambulatory settings to the general public, public policymakers, payers, other healthcare professionals, and healthcare organization decision-makers; further,

To provide ASHP information and recruitment materials highlighting opportunities for pharmacy careers in acute and ambulatory settings.

(Note: This policy would supersede ASHP policy 0703.)

Rationale

The success of ASHP's advocacy efforts relies on public perception of the pharmacists, student pharmacists, and pharmacy technicians we represent. Promoting the image pharmacy, which consistently ranks among the most trusted professions, is an ongoing priority for ASHP. In addition, as stated in the ASHP Statement on Professionalism, one of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission. The recruitment of pharmacists and pharmacy technicians begins in high school or even earlier, when students are exploring potential careers. ASHP is committed to highlighting opportunities for pharmacy careers in acute and ambulatory care settings to maintain a pool of quality candidates for those careers.

Background

The Council reviewed ASHP policy discussed ASHP policy 0703, Image of and Career Opportunities for Hospital and Health-System Pharmacists, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To ~~sustain and enhance the public information program promoting~~ promote the professional image of ~~hospital and health-system~~ pharmacists and pharmacy technicians who work in acute and ambulatory settings to the general public, public policymakers, payers, other healthcare professionals, and ~~hospital and health-system~~ healthcare organization decision-makers; further,
>
> To provide ASHP information and recruitment materials ~~identifying~~ highlighting opportunities for pharmacy careers in ~~hospitals and health systems~~ acute and ambulatory settings.

5. Practice Sites for Colleges of Pharmacy

To discontinue ASHP policy 0315, Practice Sites for Colleges of Pharmacy, which reads:

To encourage practitioner input in pharmacy education; further,

To encourage that institutional and health-system environments be used as sites for experiential training of pharmacy students; further,

To encourage colleges of pharmacy and health systems to define and develop appropriate organizational relationships that permit a balance of patient care and service, as well as educational and research objectives, in a mutually beneficial manner; further,

To include the administrative interests of both the health system and the college of pharmacy in defining these organizational relationships to ensure compatibility of institutional (i.e., health system or university) and departmental (i.e., pharmacy department and department in the college) objectives; further,

To encourage pharmacists and pharmacy leaders to recognize that part of their professional responsibility is the development of new pharmacy practitioners.

Background

The Council determined to discontinue ASHP policy 0315 and revise ASHP policy 0804 by including portions of policy 0315 in the new policy recommendation.

6. Pharmacy Practice Training Models

To promote pharmacy practice training models that: (1) provide experiential and residency training in interprofessional patient care; (2) use the knowledge, skills, and abilities of student pharmacists and residents in providing direct patient care; and (3) promote use of the pharmacist layered learning model; further,

To support the assessment of the impact of these pharmacy practice training models on the quality of learner experiences and patient care outcomes.

(Note: This policy would supersede ASHP policy 1316.)

Rationale

Pharmacy practice training models are continually evolving. The ideal training model includes characteristics such as flexibility to be useful in all patient care settings, providing patient care

through an interprofessional team, and allowing team members to practice at the top of their licenses. Many healthcare organizations are successfully employing the layered learning approach to residency and student pharmacist training, in which a pharmacist oversees multiple residents, students, and sometimes generalist pharmacists. Each member of this pharmacy team is integrated into a patient care team, with specific roles and responsibilities, but each also has accountability to the supervising pharmacist. The layered learning model may be more practical in larger institutions, which have more staff, residents, and students than smaller hospitals. It is important to individualize the training program to the practice site and its corresponding practice model.

Background

The Council reviewed ASHP policy 1316, Pharmacy Resident and Student Roles in New Practice Models, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To promote pharmacy practice ~~and~~ training models that: (1) provide experiential and residency training in ~~team-based~~ interprofessional patient care; (2) ~~recognize and~~ ~~utilize~~ use the skills, ~~and~~ knowledge, and abilities of student pharmacists and residents in providing direct patient care ~~services~~; and (3) promote use of the pharmacist layered learning model ~~augment the patient care services of pharmacists through expanded roles for residents as practitioner learners; and (4) where appropriate, utilize an approach to learning and service in which a supervising pharmacist oversees the services of students, residents, and other pharmacists providing direct patient care~~; further,
>
> To support the assessment of the impact of these pharmacy practice ~~and~~ training models on the quality of learner experiences and patient care outcomes.

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.)

- Education and Training in Healthcare Informatics (1317)

Other Council Activity

Joint Council and Commission Meeting on Clinician Well-Being and Resilience

In June 2017, ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience. The Action Collaborative is a joint effort of 55 participants representing professional organizations, government, technology and software vendors, large healthcare centers, and payers. The goals of the Action Collaborative are to (1) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance solutions that reverse the trends in clinician stress, burnout, and suicide. The Action Collaborative has created four workgroups focused on different aspects of the effort: research, data, and metrics; messaging and communications; conceptual model; and external factors and workflow. Although ASHP will participate in all the activities of the Collaborative, its two staff representatives are members of the Conceptual Model Working Group, whose goal is to develop a model that describes the internal and external factors that drive a culture of clinician well-being and resilience.

Graduating Student Survey

The Council discussed the American Association of Colleges of Pharmacy 2017 Graduating Student Survey Reports (the 2017 Graduating Student National Summary Report, 2017 Graduating Student Public School Summary Report, and the 2017 Graduating Student Private School Summary Report). Council members discussed several survey findings, including a difference in ranking of introductory pharmacy practice experiences (IPPE) versus advanced pharmacy practice experiences (APPE) rotations, and concluded that this may be a reflection of student pharmacists not understanding how IPPE rotations fit into the educational process and the need to continue incorporating teaching innovations, such as live experiences or simulation-based experiences, into the classroom.

Residency Program Accreditation: Meeting the 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. Dr. Silvester shared information on ASHP-accredited pharmacy residency growth in the last year and noted that 26 programs to date have been added and that there has been a 17% growth in the number of residency programs over two years. It was also noted that although the absolute number of pharmacy graduates is decreasing, the number of graduates seeking a residency has increased approximately 30%. Additionally, it was reported that the number of PGY2 residencies is growing more rapidly than PGY1 residencies. Ambulatory care residencies continue to grow at the fastest rate.

Pharmacy Technician Stakeholders Consensus Conference Proceedings

The Council discussed published outcomes of the Pharmacy Technician Stakeholders Consensus Conference, a national consensus conference that engaged all sectors of pharmacy in identifying points of agreement regarding entry-level requirements for pharmacy technicians. The increased availability of distance learning programs has changed the issue of access to technician education programs for remote locations without local programs. The Council continued support for the 2020 goal that the completion of a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required to obtain PTCB certification for all new pharmacy technicians.

Interprofessional Competencies

The Council discussed interprofessional education (IPE), which is widely recognized as members or students of two or more professions associated with health or social care, engaged in learning with, from, and about each other to enable effective collaboration and improve health outcomes. The recommendation from the ASHP House of Delegates was to determine whether there are policy gaps around interprofessional education in ASHP policy and residency competencies, including the interprofessional clinical learning environment. After review of existing ASHP policy and PGY1 and PGY2 competency area goals and objectives (CAGO) lists, Council members felt that ASHP policy and residency standards were heavily weighted toward interprofessional education. ASHP's upcoming participation in the National Collaborative for Improving the Clinical Learning Environment (NCICLE) Interprofessional Clinical Learning Environment Symposium, where the intent is to enhance a national conversation that seeks to identify ways to assist clinical learners to embrace interprofessional collaboration and learning was discussed.