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House of Delegates

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

COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATION

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*

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

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*

Unit Dose Packaging Availability

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that reduces medication waste; further,

To urge the Food and Drug Administration to support this goal in the interest of public health and healthcare worker and patient safety.

(Note: This policy would supersede ASHP policy 0309.)

Rationale

The benefits of unit dose drug administration were well established in the 1960s. Despite these benefits, some drugs are not available from manufacturers in unit dose packages. One reason sometimes cited for this lack of availability is that because unit dose packages make up a relatively small portion of business for many manufacturers, some manufacturers are making a business decision to discontinue this form of packaging. When manufacturers do not provide drugs in unit dose form, the pharmacy must repackage them, introducing opportunities for error. Although it may not be practical for FDA to mandate unit dose packaging to improve public health and patient safety, FDA could encourage such packaging in other ways, such as by developing packaging guidelines for the pharmaceutical industry. In cases in which unit dose

packaging is not practical, manufacturers should at a minimum provide package sizes that reduce medication waste.

Background

The Council discussed ASHP policy 0309 as part of sunset review and recommended revising the policy as follows (underline indicates added text):

> To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that reduces medication waste; further,
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> To urge the Food and Drug Administration to support this goal in the interest of public health and healthcare worker and patient safety.

The Council concluded that the policy needed to be revised because there continues to be medications that are either not available in unit dose packages or have requirements the medication is kept in its original packaging. This results in the need for additional healthcare worker manipulation of medications in order to dispense and optimize the safety of bar-code scanning of medications, which also increases exposure to medication handling and can introduce opportunities for error. Additionally, the Council concluded in cases where unit dose packaging was not available at minimum institutional package sizes that reduced waste should be encouraged by manufacturers.

Gene Therapy

To assert that health-system decisions on the selection, use, and management of gene therapy agents should be managed as part of the medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness , and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; further,

To advocate that gene therapy be documented in the permanent patient health record; further,

To advocate that documentation of gene therapy in the permanent patient health record accommodate documentation by all healthcare team members, including pharmacists.

(Note: This policy would supersede ASHP policy 0103.)

Rationale

The first biologics license agreement for a gene therapy product was submitted to the Food and Drug Administration in May 2017. Gene therapy is an emerging area of medicine, and pharmacists should take a leadership role in managing these therapies and associated devices under the medication formulary systems in their institutions.

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. It is important that gene therapy be documented in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of therapies on patient outcomes and that all healthcare providers involved in providing gene therapy, including pharmacists, be able to document the patient care provided.

Background

The Council reviewed ASHP policy 0103, Gene Therapy, as part of ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The first biologics license agreement for a gene therapy product was submitted to the Food and Drug Administration in May 2017. Gene therapy is an emerging area and pharmacists should take a leadership role over and take accountability for decisions related to it. The Panel in making its recommendation discussed the importance of having the formulary management process include the management of all gene therapy–related decisions to ensure that gene therapy and associated devices be addressed through and within the purview of the medication formulary system. It is important that gene therapy be documented in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of therapies on patient outcomes. The Council voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To ~~declare~~ assert that health-system decisions on the selection, use, and management of gene therapy agents should be managed as part of the ~~based on the same principles as a~~ medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness , and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; further,
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> To advocate that gene therapy be documented in the permanent patient health record; further,
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> To advocate that documentation of gene therapy in the permanent patient health record accommodate documentation by all healthcare team members, including 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.

Medications Derived from Biologic Sources

To discontinue ASHP policy 0809, Medications Derived from Biologic Sources, which reads:

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

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

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

Background

The Council discussed ASHP policy 0809 as part of sunset review. The Council felt this policy was redundant with ASHP policy 0232, Pharmacist's Role in Drug Procurement, Distribution, Surveillance, and Control, because management of medications derived from biologic sources has become a routine part of pharmacy practice and there is no longer a need for a policy specifically on the topic.

Role of Pharmacists and Business Leaders in Health Care Services and Policies

To discontinue ASHP policy 9819, Role of Pharmacists and Business Leaders in Health Care Services and Policies, which reads:

> To support the principle that business leaders and health professionals must share responsibility and accountability for providing optimal health care services to patients; further,
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> To support the principle that business leaders should expect practicing pharmacists to formulate policies that affect the prerogative of pharmacists to make optimal care decisions on behalf of patients.

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to discontinue the policy because elements of the policy have been incorporated into other ASHP policies (i.e., ASHP policies 1618, 1416, 1417, and 1114), making this policy redundant.

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*

Confidence in the U.S. Drug Approval and Regulatory Process

To support and foster legislative and regulatory initiatives designed to improve public and professional confidence in the drug approval and regulatory process in which all relevant data are subject to public scrutiny.

(Note: This policy would supersede ASHP policy 9010.)

Rationale

Patients, healthcare providers, and private and public payers need objective, authoritative, and reliable evidence about drugs in order to make the best treatment decisions. The basis of the trust in the Food and Drug Administration (FDA) drug approval and regulatory process is public scrutiny of the data used in its decision-making. ASHP supports efforts to improve public and professional confidence in the FDA's drug approval and regulatory process by expanding public access to relevant data used in FDA decision-making.

Background

The Council agreed with the Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel's recommendation to amend ASHP policy 9010, Generic Pharmaceutical Testing, as follows (~~strikethrough~~ indicates deleted text):

To support and foster legislative and regulatory initiatives designed to improve ~~and~~

~~restore~~ public and professional confidence in the drug approval and regulatory process in which all relevant data are subject to public scrutiny.

The Council further agreed with the Advisory Panel's recommendation that the policy's title be changed to reflect the need for public confidence in the entire U.S. drug approval and regulatory process.

Size, Color, and Shape of Drug Products

To discontinue ASHP policy 8310, Size, Color, and Shape of Drug Products, which reads as follows:

> To approve the authority of manufacturers to copy the size, shape, and color of generically equivalent drug products as a means of promoting better patient compliance (rational drug therapy), but only when the source and identity of the product are readily ascertainable from a uniform mark or symbol on the product.

Background

The Council discussed ASHP policy 8310 as part of sunset review and concluded it was no longer needed as it has become longstanding Food and Drug Administration (FDA) policy. Further, the Council determined that existing ASHP policies (8709, 0020, 0817, 1509) cover the intent of this policy and that it is no longer needed.

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.

Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,

To advocate healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions; further,

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

(Note: This policy would supersede ASHP policy 1720.)

Rationale

The pharmacokinetic and pharmacodynamic properties of drugs found in drug information monographs are based on the drug's absorption, distribution, metabolism, and excretion in healthy, adult patients during Phase I of a drug's clinical trials. Many patients receiving drug

therapy do not fit this profile, and many have compromised organ function. The medical community has long recognized the need for a standardized approach to evaluating organ system dysfunction. Although there are methods to determine organ function (e.g., the Cockcroft-Gault equation for renal function or the Child-Turcotte-Pugh Classification for Severity of Cirrhosis), there is debate as to whether these methods are true indicators of organ function, as the components that comprise these equations may fluctuate based on severity and patient status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

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

Given the complex dose adjustments and variety of conditions, education of pharmacists and other healthcare professionals is critically important to appropriately treat patients.

Background

The Council reviewed ASHP policy 1720, Drug Dosing in Conditions that Modify Pharmacokinetics or Pharmacodynamics, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text):

> To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,
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> To advocate healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics; further,
>
> To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions; further,
>
> To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.

Appropriate Dosing of Medications in Patient Populations with Unique Needs

To discontinue ASHP policy 0228, Appropriate Dosing of Medications in Patient Populations with Unique Needs, which reads:

> To advocate reforms in medication-use systems, including electronic systems, and healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics.

Background

The Council reviewed ASHP policy 0228, Appropriate Dosing of Medications in Patient Populations with Unique Needs, as part of the ASHP Formulary and Pharmacy & Therapeutics Policy and Guidelines Advisory Panel recommendations. The Council was asked to review this policy in conjunction with a review of related policies (1606, Drug Dosing in Renal Replacement Therapy; 0229, Clinical Investigations of Drugs Used In Elderly and Pediatric Patients; 1515, Research On Drug Use In Obese Patients) and to determine whether policy 0228 is still needed and relevant. The Council concluded that the related policies are still needed but that policy 1720, Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics, should be updated to include the education aspects of policy 0228 and then policy 0228 should be discontinued. Policy 1720 already includes language advocating the need for electronic health records.

DEA Scheduling of Hydrocodone Combination Products

To discontinue ASHP policy 1314, DEA Scheduling of Hydrocodone Combination Products, which reads:

> To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone combination products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

Background

The Council reviewed this policy as a part of sunset review and found that the policy was no longer necessary due to the 2014 rescheduling of hydrocodone combination products, which has led to changes in prescribing habits, increased scrutiny through state prescription monitoring programs, and a decrease in dispensing of hydrocodone combination products.