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House of Delegates

Board of Directors Report: Policy Recommendations for the March 2017 Virtual House of Delegates

as of February 2, 2017

COUNCIL ON PHARMACY MANAGEMENT POLICY RECOMMENDATION

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

Timothy R. Brown, *Board Liaison*

Ensursing Patient Safety and Data Integrity During Cyber-attacks

To advocate that healthcare organizations include pharmacists in (1) assessing cyber-security systems and procedures for vulnerabilities, (2) implementing cyber-security strategies, and (3) reviewing cyber-security breaches and developing corrective actions; further,

To encourage the development of business continuity plans by pharmacy departments; further,

To advocate that healthcare organizations assess vendor systems to validate the security and integrity of data, including an assessment of the minimum amount of patient health information vendors require to provide services.

Rationale

As use of technology in healthcare has increased, so has the risk of cyber-attacks on this essential infrastructure. The digitization of patient records and the movement to enhance healthcare with technology has increased the risk of cyber-attacks; from 2015 to 2016, there was a 5.2% increase in such attacks against healthcare targets. Moreover, healthcare facilities made up 7.1% of the identified targets in July 2016, a 5.3% increase from previous month. Maintaining the privacy of health information, in compliance with the Health Insurance Portability and Affordability Act (HIPAA), and ensuring patient safety in the face of cyber-attacks have become an essential concern for every healthcare organization. In July 2016, the U.S. Department of Health and Human Services released guidance on ransomware and HIPAA.

Despite this guidance, there remains very little assistance to prevent data breaches or advice on how to respond when an attack occurs. Increased connectivity with vendor systems creates a mutual need to share access to patient information and other vital data, so risk mitigation must be considered at all points of access. Pharmacists and pharmacy departments need to contribute to organizational efforts to prevent and respond to cyber-attacks as well as develop business continuity plans to ensure they can meet patient needs and protect patient privacy in case of such attacks.

Background

The Council discussed how every industry has felt the reach of cyber-terrorism, including the healthcare sector. The Council discussed recent U.S. cases in which healthcare organizations had significant health information technology (HIT) incidents, including ransomware, employee mismanagement of data, and phishing email breaches. The Council discussed elements needed to help secure an organization's electronic information and agreed that the key to preventing or surviving such an attack is preparation. The first step in preparation is education about what cyber-attacks are and the damage they can cause. Cyber-attacks have the potential to disable entire HIT systems, alter or erase files, employ the organization's computer systems as a weapon to attack others, and steal confidential information. If not prevented, cyber-attacks create a significant security concern by threatening to damage or destroy healthcare organizations' HIT infrastructure and inflict millions of dollars in damage. Given the potential for damage, the U.S. government and various vendors offer guidance and support on how to secure systems; however, the security of these systems also relies on strategic planning and a culture of safety.

The Council discussed topics ASHP policy should address as well as potential activities for ASHP to consider to support members, including (1) educating pharmacists about new HIT risks and accountabilities (e.g., HIPPA and cyber-attack risk management); (2) developing guidance documents; (3) promoting safe use of portable and external data storage vehicles (e.g., jump drives, Dropbox, the Cloud); and (4) encouraging development of business continuity plans in the event of an HIT system failure.

COUNCIL ON PHARMACY PRACTICE
POLICY RECOMMENDATION

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.

Reduction of Unused Prescription Drug Products

To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,

To advocate for research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, including but not limited to partial fills or refills; further,

To advocate that pharmacists take a leadership role in reducing excess quantities of unused prescription drug products.

Rationale

According to the Centers for Disease Control and Prevention (CDC), almost 5% of the U.S. population over 12 years old used prescription pain relievers for non-medical reasons in 2010, resulting in 15,000 overdose deaths. A major source of diversion is unused prescription drug products, such as those left over after a patient has gained relief from temporary pain. Although prescribers and other healthcare providers have long been aware of the dangers of unused prescription drug products, incentives for overprescribing remain. The desire to minimize office visits, concern about undertreatment of pain, and prohibitions against partial fills and refills of controlled substances contribute to overprescribing.

ASHP recognizes the need for research on best practices to ensure appropriate quantities of drug products are prescribed, which will include study of the effectiveness of

partial fills or refills of prescription drug products, among other solutions. ASHP has concerns about quantity and duration limits, because rigid restrictions on treatment options may result in adverse patient outcomes.

Appropriate community return and disposal of excess prescription drug products reduce diversion, accidental poisoning risk, and environmental harm. ASHP advocates for pharmacist leadership in reducing excess quantities of unused prescription drug products through appropriate pain management practices and development and implementation of prescription drug product return and disposal programs.

Background

The Council discussed two related issues, prescribing appropriate quantities of opioids and partial fills of opioid prescriptions. The Council noted that the Council on Public Policy was developing proposed policy on the legal aspects of partial fills and chose to focus on one of the objectives of partial fills, reduction of excess prescription drug products in the community. The Council considered ASHP policy position 1603, Stewardship of Drugs with Potential for Abuse, and ASHP policy position 0614, Safe Disposal of Patients' Home Medications, in drafting this policy recommendation. The Council noted that policy 1603 promotes "judicious" use of drugs with potential for abuse and wanted to craft a complementary policy that would encourage development of methods to ensure appropriate quantities of drug products are prescribed. This policy recommendation also complements policy 0614 by including return programs among the tools to apply to prescription drug product disposal.

COUNCIL ON PUBLIC POLICY
POLICY RECOMMENDATION

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

Ranee M. Runnebaum, *Board Liaison*

Collaborative Drug Therapy Management

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

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

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

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

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

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

Rationale

Although more than 43 states permit collaborative drug therapy management (CDTM), there is great variability in the authority granted to pharmacists engaged in CDTM. ASHP supports CDTM and advocates its expansion to all states, in a variety of diverse practice settings, and at

the highest level of pharmacy practice. As new pharmacy practice models emerge, CDTM should be a part of those innovations. One of the common barriers to the highest level of CDTM is the prohibition of pharmacists transmitting prescriptions electronically under CDTM protocols. The expansion of CDTM, including electronic transmission of prescriptions, will aid in moving the profession forward to the highest level of interprofessional, team-based practice and will enable pharmacists to practice at the top of their licenses, accountable to the patient and the team for medication-related outcomes.

Background

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

> To pursue the development of federal and state ~~legislative and regulatory provisions~~ laws and regulations that authorize collaborative drug therapy management by pharmacists; further,
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> To advocate expansion of federal and state ~~legislative and regulatory provisions~~ laws and regulations that optimize pharmacists' ability to provide the full range of professional services within their scope of expertise; further,
>
> To advocate for state laws and regulations that would allow pharmacists to transmit prescriptions electronically under collaborative drug therapy management protocols; further,
>
> To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication-related outcomes; further,
>
> To support affiliated state societies in the pursuit of state-level collaborative drug therapy management authority for pharmacists.

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

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

additional action items by ASHP are warranted. The Council made the following recommendations:

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

COUNCIL ON THERAPEUTICS
POLICY RECOMMENDATIONS

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

Donald E. Letendre, *Board Liaison*

Drug Dosing in Diseases That Modify Pharmacokinetics or Pharmacodynamics

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

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and systemic documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic disease states; 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.

Rationale

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

and disease status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

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

Background

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

Pharmacist's Leadership Role in Anticoagulation Therapy Management

To advocate that pharmacists provide leadership in caring for patients receiving medications for anticoagulant therapy management; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications for anticoagulation therapy management; further,

To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

(Note: This policy would supersede ASHP policy 0816.)

Rationale

As medication experts, pharmacists are well poised to play a key role in implementation, maintenance, monitoring, management of complications, risk assessment, and assurance of continuity of care for patients receiving medications for management of anticoagulation therapy. Inappropriate medication-related management of anticoagulants creates unnecessary preventable harm.

The Joint Commission 2008 National Patient Safety Goals for hospitals include a requirement for reducing the likelihood of harm associated with anticoagulant therapy. Healthcare facilities are instructed to assign leadership for ensuring compliance with this requirement, standardize therapeutic practices and protocols, establish monitoring procedures and a drug–food interaction program, individualize care for each patient receiving these treatments, and provide education on the appropriate management of these patients.

Background

The Council reviewed ASHP policy 0816 as a part of the discussion of the clinical measures for pharmacy accountability recommended by the 2014 Pharmacy Accountability Measures Work Group and recommended amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To advocate that pharmacists provide leadership in ~~the interdisciplinary~~ ~~interprofessional development, implementation, maintenance, effectiveness monitoring, monitoring, and assurance of continuity of care of~~ caring for patients receiving medications for anticoagulation therapy management ~~programs~~; further,
>
> To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications for ~~within~~ anticoagulation therapy management ~~programs~~; further,
>
> To encourage pharmacists who participate in anticoagulation therapy management ~~programs~~ to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team ~~staff~~ about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

The Council reviewed all ASHP policy positions, statements, and guidelines and recommended amending policy 0816 to reflect current practice and issues pharmacist may manage, including management of complications, assessment, reversal, and access, especially with the increase in prescribing of novel oral anticoagulants.