House of Delegates

Board of Directors Report:
Policy Recommendations for the
March 2020 Virtual House of Delegates

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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.

Julie A. Groppi, Board Liaison

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Jennifer Wang Tomlinson, Student (Colorado)
Jillanne Schulte Wall, Secretary

1. Definition of Meaningful Use of Health Information Technology

To discontinue ASHP policy 1006, Definition of Meaningful Use of Health Information Technology, which reads:

To advocate to policymakers (public and private) that definitions of "meaningful use of health information technology" address interoperability of medication orders and prescriptions, medication decision support and continuous improvement, and quality reporting; further,

To advocate with respect to interoperability of medication orders and prescriptions that (1) a common medication vocabulary be mandated to promote the semantic interoperability of medication use across the continuum of care, because a common vocabulary is essential for comparative effectiveness research and for communicating medication information; and (2) communication of orders and electronic prescriptions must be demonstrated to be functional and semantically interoperable with pharmacy
Background
The Council reviewed ASHP policy 1006, Definition of Meaningful Use of Health Information Technology, as part of sunset review and voted to recommend that the policy be sunsetted. The Council agreed that “meaningful use” is outdated terminology and that a policy for meaningful use is no longer needed. The Council further recommended that the Section on Pharmacy Informatics and Technology (SOPIT) review the policy and determine whether new policy is needed and which topics it should address.

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<td>To advocate with respect to medication decision support and continuous improvement that (1) medication decision support should include but not be limited to allergy, drug interaction (e.g., drug-lab or drug-disease interactions), duplicate therapy, and dose-range checking; and (2) that such a decision-support service must include an ongoing, continuous improvement process to attune the decision-support service to the needs of the providers who use it; further,</td>
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<td>To advocate with respect to quality reporting that the ability to quantify improved patient safety, quality outcomes, and cost reductions in the medication-use process is essential, particularly in antimicrobial and adverse event surveillance.</td>
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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.

Nish Kasbekar, Board Liaison

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<th>Council Members</th>
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<td>Snehal Bhatt, Chair (Massachusetts)</td>
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### 1. Safety and Effectiveness of Ethanol for Prevention or Treatment of Alcohol Withdrawal Syndrome

1. To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

2. To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to prevent or treat AWS; further,

3. To support the removal of oral or intravenous ethanol from hospital and health systems for the prevention and treatment of AWS; further,

4. To educate clinicians about evidence-based therapies for AWS.

(Note: This policy would supersede ASHP policy 1514.)
**Rationale**
AWS can delay patient recovery and interfere with response to therapy. Based on a review of the available evidence, including treatment guidelines from the American Society of Addiction Medicine (ASAM), ASHP opposes the use of oral or intravenous ethanol to prevent or treat AWS. Limited and conflicting evidence of effectiveness, inability to achieve accurate and consistent dosing and blood levels, and the availability of safer and more effective therapies are among the reasons to oppose use of ethanol to prevent or treat AWS symptoms. Benzodiazepines are the preferred drugs for the treatment of AWS, along with other supportive and adjunctive therapies as clinically appropriate. Guidelines from the American Association of Family Physicians recommend benzodiazepines on a fixed schedule for AWS, outpatient detoxification, and enrollment in an alcohol treatment program. ASHP supports efforts to prohibit use of ethanol for AWS and advocates education to a variety of healthcare practitioner audiences to increase awareness of appropriate evidence-based therapies.

**Background**
The Council reviewed ASHP policy 1514, Safety and Effectiveness of Ethanol Treatment for Alcohol Withdrawal Syndrome, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

- To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,
- To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to prevent or treat AWS; further,
- To support the removal of oral or intravenous ethanol from hospital and health systems for the prevention and treatment of AWS; further,
- To educate clinicians about evidence-based the availability of alternative therapies for AWS.

The revisions to the rationale improve the clarity and strength of ASHP’s opposition to use of oral or intravenous ethanol for AWS. The last line in the previous rationale was removed to avoid confusion and misinterpretation of these two different clinical scenarios. According to the American Academy of Clinical Toxicology practice guidelines, fomepizole and hemodialysis are preferred treatment options for acute toxic alcohol (ethylene glycol, methanol) poisoning. The Council also discussed practice around the country where enteral ethanol is still used in treatment of AWS, is a formulary item, or is able to be ordered through the electronic medical record. These examples, along with the anticipated ASAM updated guidelines to be released later in 2019, solidified the need to update this policy.
2. Excipients in Drug Products

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To encourage manufacturers to publicly disclose all excipients in drug products; further,

To advocate that the Food and Drug Administration require manufacturers to declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate, expand, and maintain interoperable information about excipients; further,

To promote research that evaluates the safety of excipients to guide clinical practice and to support the reporting and dissemination of this information via published literature, registries, and other mechanisms; further,

To foster education on the potential adverse events that may be caused by excipients; further,

To encourage documentation of allergic reactions or intolerances to or restrictions on specific excipients in the health record.

(Note: This policy would supersede ASHP policy 1528.)

Rationale

Excipients are intended to be inactive ingredients that assist in delivering a pharmaceutically elegant medication. Ideally, excipients should have a specific purpose, including serving as a binder, disintegrant, solubilizer, preservative, or for pH adjustment for the proper performance of the dosage form. The properties of the final dosage form (e.g., stability) are, for the most part, highly dependent on the excipients chosen, their concentrations, and interaction with both the active compound and each other. Poor aqueous solubility and rate of dissolution are often the two critical factors that affect the formulation and development process and as a result, some formulations of medications may include high percentages of excipients to ensure the active ingredients are able to be delivered. However, some excipients are added to formulations to enhance color or texture and are not necessary for a stable and soluble product.

In some patients, however, excipients may cause adverse events or aggravate medical conditions. Examples include patients with a red-dye allergy reacting to a suspension containing...
red dye, fillers that have a high carbohydrate content breaking ketosis in patients who are on a ketogenic diet for seizure management, exacerbation of kidney dysfunction in patients receiving a parenteral solution containing cyclodextrins, or metabolic ketoacidosis requiring dialysis in patients who are receiving high amounts of propylene glycol. Additionally, these adverse effects are not always well known or studied.

Inclusion of excipients in drug product labeling, including their derivative source would allow substitution of a nonallergenic alternative, modification of therapy (such as giving a tablet instead of a dextrose containing suspension), closer monitoring of organ function, or ordering pertinent lab values that may alert practitioners to toxicities associated with excipients as opposed to the active drug.

Additionally, many patients and providers are unaware of the potential impact that excipients may have when selecting therapies and monitoring for adverse events. Currently, the FDA only provides guidance on excipient safety for new products but does not require it unless specific regulatory or statutory requirements are cited. These guidance documents do not establish legally enforceable responsibilities nor do they require the manufacturer to disclose these excipients unless specifically requested by the FDA. Conversely, the European Union requires manufacturers to declare excipients on labelling if the medicinal product is an injectable, topical, or an eye preparation, as well as requiring excipients known to have a recognized action or effect to be declared on the labelling of all other medicinal products.

Education of manufacturers, pharmacists and other healthcare professionals, and patients regarding the use and potential adverse effects of excipients will be required. Medication-related databases will need to be configured and continuously updated to include information about drug product excipients, and electronic health record systems will need to permit documentation of allergies and medical conditions related to excipients.

Background
The Council reviewed ASHP policy 1528, Excipients in Drug Products, as part of sunset review and updated the policy to make the policy broader and to include consideration for adverse events that may be related to excipients in medications outside of allergic reactions. Some excipients may cause adverse events due to toxic accumulation or may need to be excluded due to dietary or clinical needs (such as dextrose in ketogenic diet seizure patients). The Council recommended amending the policy as follows (underscore indicates new text; strikethrough indicates deletions):

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To encourage manufacturers to publicly disclose all excipients in drug products; further,

To advocate that the Food and Drug Administration require manufacturers to declare the name and derivative source of all excipients in drug products on the official label; further,
To advocate that vendors of medication-related databases incorporate, expand, and maintain interoperable information about excipients; further,

To promote research that evaluates the safety of excipients to guide clinical practice, and to support the reporting and dissemination of this information via published literature, registries, and other mechanisms; further,

To foster education on the allergenicity potential adverse events that may be caused by excipients and documentation in the patient medical record of allergic reactions to excipients; further.

To encourage documentation of allergic reactions or intolerances to or restrictions on specific excipients in the health record.

3. Gabapentin as a Controlled Substance

1. To advocate that the Drug Enforcement Administration reschedule gabapentin to Schedule V due to its low potential for abuse and patient harm.

Rationale

Gabapentin is a structural analog of gamma-aminobutyric acid that is approved by the Food and Drug Administration (FDA) for post-herpetic neuralgia and as an adjunctive therapy for partial seizures. Gabapentin has been identified as an opportunistic drug of abuse which, when used in conjunction with other medications, particularly opioids, may result in serious adverse events such as respiratory depression and even death. Gabapentin is used due to its low cost, classification as a noncontrolled substance, and increasing rates of on- and off-label prescribing attributable to clinicians’ desire for an alternative to opioids for pain management. In the U.S., gabapentin is and remains a noncontrolled substance at the federal level despite evidence suggestive of diversion and abuse with opioids. Most recently, several states have made an effort to combat the diversion and abuse of gabapentin by examining various regulatory approaches, such as recategorization of gabapentin as controlled substance or mandating the reporting of the prescribing and/or dispensing of gabapentin to a state-level prescription drug monitoring programs (PDMPs). As recently as April 2019, the United Kingdom reclassified gabapentin as a Class C controlled substance, which required similar dispensing and monitoring as controlled substances in the U.S., due to the increase in abuse they have seen in this drug.

As defined by the Drug Enforcement Administration (DEA), Schedule V controlled substances “are defined as drugs with lower potential for abuse than Schedule IV” substances. Schedule IV substances “are defined as drugs with a low potential for abuse and low risk of dependence.” Recent data from multiple sources have shown a significant increase in gabapentin misuse, abuse, and diversion over the past 10 years, and one study found that 22% of a sample of 162 opioid-dependent patients had a prescription for gabapentin, of which 40% indicated they used more than prescribed to augment and enhance their opioid experiences.
The criteria used by DEA to determine whether to control or reschedule a drug include (a) the drug’s actual or relative potential for abuse; (b) scientific evidence of its pharmacological effect, if known; (c) the state of current scientific knowledge regarding the abuse of the drug or other substance; (d) its history or current pattern of abuse; (e) the scope, duration, and significance of abuse; (f) what, if any, risk there is to public health; (g) its psychic or physiological dependence liability; and (e) whether the substance is a precursor of a substance already controlled under the law. Based on an assessment using these criteria, gabapentin is similar to other controlled substances found in Schedule V and should therefore be assigned to Schedule V. Because some states have already taken steps to reschedule gabapentin as Schedule V or have added it to their PDMPs, the DEA should take steps to change the schedule status of gabapentin to ensure continuity of care and monitoring.

While it is difficult to predict the impact rescheduling may have on abuse, the current extent of abuse is likely exacerbated by easy access to and excessive supply of these therapies. However, the potential public health benefit of rescheduling must be weighed against concerns about restricting patients’ access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. In balancing these concerns, it should be noted that increased control of drugs with abuse potential is in the best interests of patients and public health. DEA and other stakeholders should monitor the impact of this scheduling change on patient access and practice, as well as monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

**Background**

The Council discussed the need to reschedule gabapentin from a nonscheduled drug to Schedule V under the Controlled Substance Act. The Council’s assessment included the review of the DEA criteria for drugs in Schedule V, the schedule status of the structurally similar drug pregabalin, and the reports from entities concerning the extent of abuse and patient harm. The Council discussed the necessity of the rescheduling of gabapentin to a Schedule V designation. Council members shared that they often see inappropriate prescribing in the outpatient setting in both the dose and frequency, which they believe may also be contributing to the cycle of abuse, as well as lack of an antidote. Furthermore, the Council discussed their concerns about patient access, noting that although the number of states making such a schedule change is increasing, scheduling is inconsistent across the U.S., which could lead to access and diversion issues. The Council believed that encouraging the DEA to change gabapentin’s schedule status would permit a uniform approach to monitoring and metrics.
4. Evaluation of Abuse-Deterrent Drug Mechanisms

1. To encourage manufacturers to develop safe and efficacious abuse-deterrent formulations for drugs known to be abused and misused; further,

2. To promote research on the efficacy of abuse-deterrent mechanisms in preventing prescription drug abuse, and to support the reporting and dissemination of this information; further,

3. To advocate for legislation that would limit out-of-pocket expenditures for such formulations.

(Note: This policy would supersede ASHP policy 1512.)

Rationale

The abuse of certain classes of prescription drugs, including narcotics and stimulants, has had a large impact on public health. One way the Food and Drug Administration (FDA) has sought to curb this activity is through the use of abuse-deterrent formulations (ADFs). ADFs are formulations that permit treatment of a patient’s medical condition but reduce the likelihood of diversion, misuse, and abuse, and related adverse outcomes through various mechanisms, such as hindering the extraction of active ingredients, limiting their bioavailability, preventing administration through alternative routes, or making abuse of the manipulated product less attractive or rewarding.

The FDA has been taking steps to incentivize and support the development of opioid formulations with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies, developing appropriate testing methodologies for both innovator and generic products, and publishing guidance on the development and labeling of abuse-deterrent opioids.

Despite these efforts, prescription stimulants used to treat attention deficit hyperactivity disorder have become drugs of choice for young adults, with as many as 20% of college students using such drugs for nonmedical purposes. According to a 2011 study, benzodiazepines were involved in 30.6% of prescription drug-related overdose deaths. However, to date, the FDA has not provided guidance on ADFs for any controlled substance other than opioids.

Despite the groundswell of support for abuse-deterrent opioid formulations, there is not strong evidence that such formulations deter abuse. One study of 232,874 patients across 437 facilities found an increase in abuse prevalence of all opioids after introduction of an abuse-deterrent formulation. That study showed little success in deterring abuse, finding instead that patients had switched to alternative drugs. There may also be unintended consequences of preferring abuse-deterrent formulations to regular formulations, such as increased costs borne by patients who legitimately need the drugs.
There also is a need to demonstrate that these formulations are truly abuse deterrent as well. In April 2015, the FDA published an industry guidance document on Abuse-Deterrent Opioids – Evaluation and Labeling. The document explains the FDA’s “current thinking about the studies that should be conducted to demonstrate a given formulation has abuse-deterrent properties.”

Addressing the growing rate of prescription drug abuse will require a multifaceted strategy; no one tactic will solve the problem. While ASHP supports measures such as abuse-deterrent formulations and rescheduling to prevent abuse, more research is necessary to determine which tactics are the most effective at deterring abuse.

**Background**

The Council reviewed ASHP policy 1512, Development of Abuse-Resistant Narcotics, as part of sunset review. The Council recommended that ASHP continue to advocate for investigating drug formulations for all drugs that carry a high level of misuse and abuse (e.g., opioids, stimulants).

The Council voted to recommend amending the policy as follows (underscore indicates new text; strikethrough indicates deletions):

To encourage manufacturers to develop safe and efficacious abuse-deterrent formulations for drugs known to be abused and misused; further,

To promote research on advocate that the Food and Drug Administration investigate the efficacy of abuse-deterrent mechanisms resistant formulations in preventing prescription drug abuse, and to support the reporting and dissemination of this information; further,

To advocate for legislation that would limit out-of-pocket expenditures for such formulations.

### 5. Anticancer Treatment Parity

1. To support anticancer treatment parity legislation at both the state and federal level that ensures equality of access and insurance coverage for all anticancer drug products approved by the Food and Drug Administration (FDA); further,

2. To advocate all insurers and manufacturers design plans containing limits on out-of-pocket expenditure so that patient cost sharing for anticancer treatment is equivalent, regardless of treatment modality or route of administration; further,

3. To encourage the development of policies and endorse practices that contribute to a decrease in anticancer treatment costs to the consumer; further,
To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of anticancer agents, regardless of route of administration.

(Note: This policy would supersede ASHP policy 1516.)

Rationale
An estimated $200 billion will be spent on cancer care by 2020, and a recent survey showed if faced with a cancer diagnosis, 57% of Americans say they would be most concerned about either the financial impact on their families or about paying for treatment. Additionally, there is an increase in insurance premiums, co-pays, co-insurance, and deductibles. Most insured cancer patients in the U.S. are responsible for a portion of the cost of their anticancer agents, which can be significant. The average out-of-pocket expense for Medicare patients with cancer is 23.7% of household income. Cancer survivors are 2.7 times more likely to file for bankruptcy.

Traditionally, intravenous (IV) and injected treatments were the primary methods of chemotherapy delivery. Patient-administered anticancer agents have become more prevalent and are now the standard of care for many types of cancer. Oral anticancer agents account for approximately 35% of the oncology development pipeline. Many oral anticancer agents do not have infusible or injectable alternatives, and are the only treatment option for some cancer diagnoses. Oral agents have been embraced because of convenience, efficacy, and safety, but because insurers cover them differently than intravenous drugs, prescribing oral anticancer agents can impose burdensome levels of cost-sharing on patients.

While IV anticancer treatments are covered under a health plan’s medical benefit, often requiring patients to pay a minimal co-pay or no cost at all for the medication, oral anticancer agents are usually covered under the pharmacy benefits. This results in increased out-of-pocket costs. Cost sharing of oral specialty drugs has increased from 3% in 2004 to 25% in 2013, and continues to rise.

The impact of rising out-of-pocket prescription costs for cancer patients can negatively affect adherence and subsequently treatment outcomes. Co-pays can be hundreds or thousands of dollars per month and, as a result, almost 10% of patients choose not to fill their initial prescriptions for oral anticancer agents. A study of claims data from more than 38,000 people who received a new prescription for one of 38 oral anticancer agents from 2014 to 2015 found that, as out-of-pocket costs rose, fewer patients filled their prescriptions. When the required co-pay was less than $10, only 10% of patients failed to pick up their prescriptions. This increased to 32% for patients whose out-of-pocket costs were between $100 and $500, and to 41% when costs were between $500 and $2000. When the out-of-pocket costs exceeded $2000, nearly half of patients (49%) never filled their prescriptions. Delayed initiation of treatment was also significantly higher for those with higher cost-sharing burdens.

Oral parity is a proposed legislative solution to alleviate coverage discrepancies between oral and intravenous anticancer agents. Parity laws are currently state laws designed to ensure that orally administered agents for treating cancer are not more costly for patients than anticancer agents given via infusion at a clinic or hospital. At this point, 43 states and
Washington, DC, have enacted parity laws that require patients to pay no more for an oral cancer treatment than they would for an infusion.

However, state parity laws only apply to certain commercial health insurance plans, including those purchased by small groups and individuals. Self-funded patients, patients covered by health plans that fall under federal law (large, multi-state health plans), or those covered by Medicare and other federally funded insurance plans are not eligible. An estimated fifty percent of cancer patients are currently not protected under state parity laws.

The Cancer Drug Parity Act of 2019 (H.R. 1730, introduced on March 13th, 2019; formerly introduced in 2017 as H.R. 1409) would require any health plan that currently provides coverage for cancer treatment to provide coverage for self-administered anticancer agents at a cost no less favorable than the cost of IV, port-administered, or injected anticancer agents.

There may be false patient perception that oral anticancer agents are less dangerous than IV chemotherapy, furthering supporting the important role of the pharmacist in educating the patients about the agent, its adverse effects, how to manage toxicities, and when to contact their healthcare team. Pharmacists monitor oral chemotherapy treatments to prevent medication and food interactions, adverse drug reactions, and medication errors. Pharmacists are also positioned to play an integral role in shared decision-making and assisting with procurement.

Treatment of cancer also continues to evolve, and many agents may not fall under the category of traditional chemotherapy (e.g., biologic agents, antimicrobials, and others). As a result, practitioners and legislatures have moved away from the singular term chemotherapy and use chemotherapy, anticancer and cancer drug interchangeably, with anticancer being the preferred term.

Background
The Council reviewed ASHP policy 1516, Chemotherapy Parity, as part of sunset review. To ensure the policy is comprehensive and current, to advocate for impactful and inclusive parity legislation on both the state and national level, and to recognize pharmacists play a key role in advocating for patient access to chemotherapy medications, regardless of route of delivery, the council and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To support anticancer treatment parity legislation at both the state and federal level that ensures equality of access and insurance coverage for all anticancer drug products approved by the Food and Drug Administration (FDA); further,

To advocate all insurance payers insurers and manufacturers design plans containing limits on out-of-pocket expenditure so that patient cost sharing for chemotherapy anticancer treatment be is equivalent, regardless of treatment modality or route of administration; further,

To encourage the development of policies and endorse practices that contribute to a decrease in anticancer treatment costs to the consumer; further,
To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of chemotherapy anticancer agents, regardless of route of administration.

6. Quality Consumer Medication Information

- To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, accessibility, targeting, and simplicity of consumer medication information (CMI); further,

- To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level and standardized, patient-focused templates, for CMI; further,

- To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

- To advocate that FDA explore alternative models of CMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency, and conforms with health literacy requirements; further,

- To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly and easily accessible central repository of CMI in a format that is suitable for ready export; further,

- To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of CMI.

(Note: This policy would supersede ASHP policy 1513.)

Rationale

ASHP supports the intent of efforts to improve the quality, consistency, and simplicity of consumer medication information (CMI). The Food and Drug Administration (FDA) defines CMI (previously called patient medication information, or PMI) as “written information about prescription drugs developed by organizations or individuals other than a drug’s manufacturer that is intended for distribution to consumers at the time of drug dispensing.” CMI is not reviewed or approved by the FDA or a drug’s manufacturer.

In the 1970s, the FDA began evaluating the usefulness of patient labeling, and in 1996, Public Law 104-180 defined PMI “usefulness” as being “scientifically accurate, unbiased in
content and tone, sufficiently specific and comprehensive, presented in an understandable and legible format that is readily comprehensible to consumers, timely and up-to-date, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm.” In 2002, the National Association of Boards of Pharmacy conducted a study on the usefulness of PMI and that found that 89% of patients in the study received some form of written PMI but that only about 50% of the PMI met the definition of usefulness.

In 2006, the FDA published guidance on useful written CMI. However, because CMI improvement efforts were largely based on consensus of expert opinion, rather than quantitative and well-documented evidence, and because subsequent studies were conducted using expert-based focus groups and other study designs that do not reflect typical patients and under flawed methodology, ASHP encourages the development of evidence-based models for CMI that are designed to support desired outcomes (e.g., better medication use, improved patient safety). In addition, research to validate the effectiveness of any new CMI models under real-use conditions by actual patients, including establishment of a universal literacy level for CMI, should be encouraged. Evidence to establish the essential CMI content needed for the safe and effective use of medications by patients remains to be determined.

Although drug information publishers have made significant progress in improving the quality of CMI, this content is often truncated or provided in illegible formats to accommodate size restrictions or marketing information on patient drug information leaflets that are stapled to prescription packaging.

Because of the FDA’s long history of failure to ensure the consistency, currency, and accuracy of the professional labeling on which CMI would be based; the potential for inclusion of biased or promotional information; and the resulting patient confusion and possible harm, ASHP strongly opposes any proposal for manufacturer-authored CMI that would not be subject to FDA review. Approximately 85% of professional labeling has not been reviewed or updated since 1992 to reflect FDA’s current standard for the Physician Labeling Rule (PLR) format. In addition, numerous inconsistencies and inaccuracies in such labeling continue. Given these limitations, the majority of information on which CMI would be based under such a regime would not be likely to “enhance the safe and effective use of prescription drug products and in turn reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information,” which is the main goal of the FDA requirements.

ASHP further advocates that state legislatures and regulatory agencies require that all dispensers distribute CMI according to FDA-established standards and be held accountable if CMI content or format is modified in a manner that results in nonconformance to the standards.

Creation and maintenance of CMI by a single third-party author (subject to FDA-contracted standards and quality assurance metrics) would provide clear, concise, unbiased, evidence-based CMI that is both timely and consistent for the same drug and for relevant information within the same drug class. Such coordination of the medication information database would allow for consistency in style and content, as well as more frequently updated content.
Due to the evolution of how information is consumed and accessed and in light of the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, ASHP also advocates that CMI also be consumable across multiple platforms, including electronic platforms, as more individuals use online medical records to better manage their health and healthcare needs. The Department of Health and Human Services has reported a steady increase in the proportion of individuals who reported having been offered access to their online medical record, with approximately three-quarters of individuals reporting having access to a current list of medications within their online medical record.

**Background**

The Council reviewed ASHP policy 1513, Quality Patient Information, as part of sunset review. The Council recommended amending the policy as follows so the policy would focus on patient-friendly CMI, increased accessibility, and current technology and terminology (underscore indicates new text; strikethrough indicates deletions):

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, accessibility, targeting, and simplicity of written patient-consumer medication information (CMI) (PMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level and standardized, patient-focused templates, for CMI PMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of CMI PMI-content development and maintenance that will ensure the highest level of accuracy, consistency, and currency, and conforms with health literacy requirements; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly and easily accessible central repository of CMI PMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of CMI PMI.
7. Pharmacist’s Leadership Role in Anticoagulation Therapy Management

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

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving drug products 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 drug product uses, drug interactions, reversal therapies and strategies, 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 1703.)

Rationale
As medication experts, pharmacists are well positioned 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.

Since 2008, The Joint Commission National Patient Safety Goals for hospitals have included a requirement for reducing the likelihood of harm associated with anticoagulant therapy. Healthcare facilities were 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. In 2019, the related elements of performance were revised to address a rise in adverse drug events associated with direct oral anticoagulants (DOACs).

Background
The Council reviewed ASHP policy 1703, Pharmacist’s Leadership Role in Anticoagulation Therapy Management, as a part of the background readings for the discussion on Clinical Utility of Drug-Specific Reversal Agents for Direct Oral Anticoagulants. The Council believed that there was not a need for a separate policy to address this clinical topic but that reversal therapies and strategies should be included in ASHP policy 1703, and that “medications” should be changed to “drug products” to be consistent with the terminology of other ASHP policies. The Council voted to recommend amending the policy as follows (underscore indicates new text; strikethrough indicates deletions):

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

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications drug products 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 drug product uses, drug interactions, reversal therapies and strategies, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

8. Use of Surrogate Endpoints for FDA Approval of Drug Uses

1. To support efforts by the Food and Drug Administration (FDA) and other stakeholders to qualify the appropriateness of surrogate endpoints; further,

2. To support the continued use of qualified surrogate endpoints by the FDA as a mechanism to evaluate the effectiveness and safety of new drugs and new indications for existing therapies, when measurement of definitive clinical outcomes is not feasible; further,

3. To advocate that the FDA consistently enforce existing requirements that drug product manufacturers complete postmarketing studies for drugs approved based on qualified surrogate endpoints in order to confirm that the expected improvement in outcomes occurs, and to require that these studies be completed in a timely manner.

(Note: This policy would supersede ASHP policy 1011.)

Rationale
Expedited approval programs provided by the FDA have resulted in substantial public health benefits, as illustrated by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. The FDA provides four mechanisms to expedite the development and review process for drugs: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The structure and requirements for each of these mechanisms differs as described in a 2013 draft guidance for industry. However, to qualify for any of these programs, a drug must (1) address an unmet medical need, (2) provide benefit over available drug treatments, and (3) be used in the treatment of a serious or life-threatening condition. Further, the FDA guidance states that these programs are “intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies’ benefits justify their risks.” Processes used to ensure a favorable
risk–benefit profile include, but are not limited to, requirements for postmarketing studies to evaluate safety and effectiveness of the drug as used in real-world scenarios. However, the accelerated approval program is the only program that includes postmarketing studies as a requirement of the program. The FDA has discretion to require additional studies on a case-by-case basis for drug products approved via the other expedited mechanisms. Despite these safeguards, some features of these programs (e.g., smaller clinical trials, alternate trial designs, or limited-duration trials) can result in increased patient risk because less is known about a drug’s side effect profile and efficacy due to limited patient exposure. In addition, as with all drugs, safety assessments benefit from use of the drug in post-approval patient populations, which better reflect real-world use than the controlled environment of a clinical trial.

Because these drugs represent medical advances, their post-approval use can be extensive. Further, off-label use of these drug products, like all therapies, is common. Unfortunately, prescribers and other clinicians are frequently unaware that an expedited pathway was utilized and that evidence limitations exist. This scenario raises significant concerns about whether there is sufficient clinician awareness to ensure appropriate use of drugs approved via these pathways. Therefore, ASHP proposes unique labeling requirements that would increase awareness through use of a logo or other mechanism that would be used on an interim basis to inform clinicians about data limitations and provide guidance on appropriate use. This labeling would describe appropriate patient populations and monitoring parameters. Similar labeling requirements have been proposed for a new pathway being considered for the development of antibiotics used to treat life-threatening infections. ASHP supports the approach, but recommends that the increased labeling requirements be discontinued once the drug product manufacturer and FDA agree that sufficient data is available to support safe and effective use, or after the drug manufacturer completes any required postmarketing study commitments.

Given data limitations associated with approval of these therapies, ASHP advocates that the FDA be extremely diligent in ensuring that postmarketing commitments are met. Further, the FDA should use its existing authority as described under 21 CFR 314 subpart H and 21 CFR 601 subpart E if timelines or expectations for these commitments are not satisfactory. This authority allows the FDA to take legal action through penalties that include requiring labeling changes or rescinding marketing approval.

Finally, ASHP believes that there is a need for research to determine whether these expedited pathways are achieving the desired benefits, which include decreasing the time and costs associated with drug product development, lowering overall healthcare costs, and increasing patient access to safe and effective drug therapies.

Background
The Council reviewed ASHP policy 1011, Use of Surrogate Endpoints for FDA Approval of Drug Uses, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

[CLAUSE MOVED]To support efforts by the Food and Drug Administration (FDA) and other stakeholders to qualify the appropriateness of surrogate endpoints; further,
To support the continued use of qualified surrogate endpoints by the Food and Drug Administration (FDA) as a mechanism to evaluate the effectiveness and safety of new drugs and new indications for existing therapies, when measurement of definitive clinical outcomes is not feasible; further,

To advocate that the FDA consistently enforce existing requirements that drug product manufacturers complete postmarketing studies for drugs approved based on qualified surrogate endpoints in order to confirm that the expected improvement in outcomes occurs, and to require that these studies be completed in a timely manner.

These amendments are intended to reflect that the use of surrogate endpoints has continued to gain traction, especially in the realm of cancer drugs, and that while surrogate endpoints are appropriate when “definitive clinical outcomes (are) not feasible,” as noted in the current policy, many surrogate outcomes are either inflating mild benefits or proving harmful. There is some interest in providing guidance on the appropriateness of the use of surrogate outcomes, but this idea has not been universally accepted and requires ASHP advocacy.
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.

Kristina L. Butler, Board Liaison

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Eric Maroyka, Secretary

1. Staffing for Safe and Effective Patient Care

To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care; further,

To encourage pharmacy leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To support the following principles:
- Sufficient qualified staff must exist to ensure safe and effective patient care;
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services; and

Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

(Note: This policy would supersede ASHP policy 0201.)

Rationale
The advancement of the pharmacy profession over the past decade has prepared and positioned pharmacists to care for complex patients and adapt to the dynamic and rapidly progressive field of medicine. Throughout the years, an increased involvement of pharmacists in specialty areas such as transplant, critical care, oncology, and pain and palliative care has been observed. Therefore, it is imperative that such advancement is considered when developing staffing models, in order to ensure the pharmacy workforce is appropriately allocated for the provision of consistent, safe, and high-quality patient care.

The complexity of patient care will continue to increase, and with that, so will the expected responsibilities, opportunities, and skills of the pharmacy workforce. Consequently, pharmacists engaged in direct patient care are encouraged to pursue and maintain their training and credentialing in order to continue to enhance their competency, skills, and participation in innovative practice. The expansion and dynamic nature of the pharmacy profession requires new approaches to explore flexible staffing models to avoid a stagnant practice, encourage continual advancement, and accommodate the evolving priorities of the pharmacy workforce.

The development and implementation of flexible staffing models can enable pharmacists to engage in further professional development and career advancement (e.g., training in areas of specialization, degree programs) and enjoy a more stable work-life integration experience. Recently, more attention has been drawn to burnout, resilience, and job satisfaction among the pharmacy workforce. Research has shown that pharmacists are reporting increased job stress over the previous years and that approximately 53% of pharmacists are reporting a high degree of burnout, which can consequently threaten patient safety. Therefore, there is an imperative to develop staffing models to meet staff members’ changing priorities and for additional flexibility in the workplace. Implementation of flexible staffing models could improve performance and joy in the workplace. Pharmacy leaders should be committed to maintaining high-quality and consistent patient care services and to also promote models that balance patient care with staff priorities.
Various options to consider when exploring flexible staffing models are remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy technicians’ roles to support pharmacist engagement in direct patient care activities. Some institutions have explored data-driven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services.

Similarly, other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, patient acuity, collaborative staffing, and supplemental staffing model. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.

**Background**

The Council reviewed ASHP policy 0201, Staffing for Safe and Effective Patient Care, and voted to recommend amending it as follows (underscore indicates new text):

To encourage pharmacy managers leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care; further,

To encourage pharmacy managers leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To support the following principles:
- Sufficient qualified staff must exist to ensure safe and effective patient care;
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services; and
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.
The Council recommended ASHP (possibly the New Practitioners Forum) survey members about the use of innovative staffing models to combat burnout and maintain well-being and resilience. Membership education on the survey results and identified best practice pearls should follow. The Council recommended ASHP update its Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel. Finally, ASHP should further support the study, publication, and promotion of such staffing models that provide flexibility for practitioners in the continuously evolving profession of pharmacy, without sacrificing consistent, safe, and high-quality patient care.

### 2. Health-System Facility Design

1. To advocate the development and the inclusion of contemporary pharmacy and medication-use specifications in national and state healthcare design standards to ensure adequate space for safe provision of pharmacy products and patient care services; further,

2. To promote pharmacist involvement in the design-planning and space-allocation decisions of healthcare facilities.

(Note: This policy would supersede ASHP policy 0505.)

**Rationale**

Often the design and location of health-system pharmacy departments are less than ideal. Many pharmacy departments do not have adequate square footage, and too often the pharmacy is located in the basement of the hospital, far removed from the patients. The impact of physical space on staff satisfaction may also contribute to staff turnover. Pharmacy design often occurs before pharmacy leadership has an opportunity for input on the design, location, or size.

Healthcare architects and facility engineers need to be knowledgeable in the contemporary and future needs of pharmacy design and the facility requirements for medication use (e.g., medication preparation rooms, temperature monitoring, automated dispensing cabinets). This includes, for instance, the inclusion of technical specifications (including those in applicable compendial standards of the United States Pharmacopeia) for pharmacies in national healthcare design standards.

Regarding facility design, pharmacist collaboration with the Association of Healthcare Engineers and the American Institute of Architects is paramount to design success. The Guidelines for Design and Construction of Hospital and Health Care Facilities is the primary document driving design decisions by architects and healthcare engineers. Research results on optimal, evidenced-based facility design to support safe medication use should be incorporated in new or renovation construction plans.
Background
The Council reviewed ASHP policy 0505, Health-System Facility Design, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text):

To advocate the development and the inclusion of contemporary pharmacy and medication-use specifications in national and state healthcare design standards to ensure adequate space for safe provision of pharmacy products and patient care services; further,

To promote pharmacist involvement in the design-planning and space-allocation decisions of healthcare facilities.

The Council discussed the desire for the policy to emphasize components of the entire medication-use process beyond the pharmacy (e.g., medication preparation rooms, temperature monitoring, automated dispensing cabinets).
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.

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Anna Legreid Dopp, Secretary

Linda S. Tyler, Board Liaison

1. Role of the Pharmacy Workforce in Identifying and Caring for Victims of Human Trafficking

1. To recognize that human trafficking is a significant public health problem in the U.S.; further,

2. To affirm that the pharmacy workforce has important roles in identifying and caring for victims of human trafficking; further,

3. To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in identifying and caring for victims of human trafficking.

Rationale
The U.S. Department of Health and Human Services Office on Trafficking in Persons (OTIP) describes human trafficking as a form of modern slavery that "occurs when a trafficker exploits an individual with force, fraud, or coercion to make them perform commercial sex or work." OTIP outlines two types of trafficking: labor trafficking, in which individuals are compelled to work or provide services; and sex trafficking, in which "adults are compelled to engage in
commercial sex by force, fraud, or coercion or minors are compelled to perform a commercial sex act regardless of the presence of force, fraud, or coercion."

Combating human trafficking is one of the central goals of the American Hospital Association Hospitals Against Violence Initiative. All healthcare providers have a role in identifying and caring for victims of human trafficking. These roles include recognizing indicators of human trafficking; being aware of common healthcare issues faced by human trafficking victims; providing for a patient’s medical and nonmedical needs while providing a safe and comfortable environment; complying with applicable laws regarding reporting of suspected human trafficking, including child abuse; and providing care and resources for survivors of human trafficking.

**Background**
The Council considered the topic of human trafficking after participating in the Joint Meeting on Violence and Firearm-related Injury and Death. The Council agreed that while human trafficking is a type of violence, a separate policy is needed to emphasize the pharmacy workforce’s role in preventing, identifying, and responding to it. Adoption of a policy will emphasize the need to raise awareness with members and external stakeholders and to promote member resource development.

2. **Use of Two Patient Identifiers in the Outpatient Setting**

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<td>To encourage the use of two identifiers to confirm patient identity when transferring filled prescriptions to the possession of the patient or patient’s agent for outpatient use.</td>
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(Note: This policy would supersede ASHP policy 1024.)

**Rationale**
Errors caused by dispensing medications to the wrong patient are largely preventable. Although two patient identifiers are routinely used when medications are administered in inpatient settings, similar practices are not employed when dispensing medications for outpatient use. ASHP supports consistent use of two patient identifiers and believes that this safety strategy should be used to confirm patient identity at the time patients or their agents pick up filled prescriptions for outpatient use.

**Background**
The Council reviewed ASHP policy position 1024, Use of Two Patient Identifiers in the Outpatient Setting, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To encourage the use of two identifiers to confirm patient identity when transferring filled prescriptions to the possession of the patient or patient’s agent in for outpatient use settings.
The Council agreed with the intent of the policy position but recommended it be amended to address all circumstances in which prescriptions are transferred, regardless of setting.

3. Prescription Drug Abuse

To discontinue ASHP policy position 1526, Prescription Drug Abuse, which reads:

- To affirm that pharmacists have leadership roles in recognition, prevention, and treatment of prescription drug abuse; further,
- To promote education on prescription drug abuse, misuse, and diversion-prevention strategies.

Background
The Council reviewed ASHP policy position 1526 as part of sunset review and voted to recommend discontinuing it because the policy position is redundant with the ASHP Statement on the Pharmacist’s Role in Substance Abuse Prevention, Education, and Assistance, and ASHP policies 1603, Stewardship of Drugs with Potential for Abuse, and 1614, Controlled Substance Diversion and Patient Access.

4. Medication Errors and Risk Management

To discontinue ASHP policy position 0021, Medication Errors and Risk Management, which reads:

- To urge that pharmacists be included in health care organizations' risk management processes for the purpose of (a) assessing medication-use systems for vulnerabilities to medication errors, (b) implementing medication-error prevention strategies, and (c) reviewing occurrences of medication errors and developing corrective actions.

Background
The Council reviewed ASHP policy position 0021 as part of sunset review and voted to recommend discontinuing it because the policy position is redundant with the ASHP Statement on the Role of the Medication Safety Leader and ASHP policies 1115, Just Culture, and 1021, Just Culture and Reporting Medication Errors.