

Government, Law, and Regulation

Automatic Stop Orders (0904)

Source: Council on Pharmacy Practice

To advocate that the Centers for Medicare & Medicaid Services (1) revise the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice.

Approval of Follow-on Biological Medications (0906)

Source: Council on Public Policy

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

To encourage research on the safety, effectiveness, and interchangeability of follow-on biological medications; further,

To support legislation and regulation to allow Food and Drug Administration approval of follow-on biological medications; further,

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

To advocate for adequate reimbursement for biological medications that are deemed interchangeable; further,

To promote education of pharmacists about follow-on biological medications and their appropriate use within hospitals and health systems; further,

To encourage pharmacist evaluation and the application of the formulary system before follow-on biological medications are used in hospitals and health systems.

(*Note:* Follow-on biological medications are also referred to as biosimilars, follow-on protein products, biogenerics, comparable biologicals, and generic biopharmaceuticals.)

This policy supersedes ASHP policy 0519.

Pharmaceutical Product and Supply Chain Integrity (0907)

Source: Council on Public Policy

To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

This policy supersedes ASHP policy 0722.

Regulation of Interstate Pharmacy Practice (0909)

Source: Council on Public Policy

To advocate that state governments, including legislatures and boards of pharmacy, adopt laws and regulations that harmonize the practice of pharmacy across state lines in order to provide a consistent, transparent, safe, and accountable framework for pharmacy practice.

Stable Funding for Office of Pharmacy Affairs (0911)

Source: Council on Public Policy

To advocate for adequate funding for the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs to support its public health mission; further,

To support initiatives of the Office of Pharmacy Affairs, including the 340B Drug Pricing Program and innovative pharmacy service models in HRSA-funded programs.

Regulation of Dietary Supplements (0811)

Source: Council on Public Policy

To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling that includes disclosure of excipients; (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and (4) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met: (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective; (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer; (3) the advertising includes a recommendation to consult with a health care professional before initiating use; (4) any known warnings or precautions regarding dietary supplement–medication interactions or dietary supplement–disease interactions are provided as part of the advertising; and (5) the advertising is educational in nature and includes pharmacists as a source of information.

(*Note:* *Dietary supplement* as used in this policy is defined by the Dietary Supplement Health and Education Act of 1994, as amended; 21 U.S.C. 321.)

This policy supersedes ASHP policy 0718.

Medicare Prescription Drug Benefit (0813)

Source: Council on Public Policy

To strongly advocate a fully funded prescription drug program for eligible Medicare beneficiaries that maintains continuity of care and ensures the best use of medications; further,

To advocate that essential requirements in the program include (1) appropriate product reimbursement; (2) affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services, based on a study of those costs; (4) appropriate coverage and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient's choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

(Note: Fully funded means the federal government will make adequate funds available to fully cover the Medicare program's share of prescription drug program costs; eligible means the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.)

This policy supersedes ASHP policy 0721.

Federal Review of Anticompetitive Practices by Drug Product Manufacturers (0814)

Source: Council on Public Policy

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

To encourage appropriate federal review of these practices.

This policy supersedes ASHP policy 0520.

Uniform State Laws and Regulations Regarding Pharmacy Technicians (0815)

Source: Council on Public Policy

To advocate that pharmacy move toward the following model with respect to technicians as the optimal approach to protecting public health and safety: (1) development and adoption of uniform state laws and regulations regarding pharmacy technicians, (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy technician certification, and (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to the state board of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

To advocate registration of pharmacy technicians by state boards of pharmacy; further,

To advocate, with respect to certification, as an interim measure until the optimal model is fully implemented, that individuals be required either (1) to have completed an ASHP-accredited program of education and training or (2) to have at least one year of full-time equivalent experience as pharmacy technicians before they are eligible to become certified; further,

To advocate that licensed pharmacists be held accountable for the quality of pharmacy services provided and the actions of pharmacy technicians under their charge.

(Note: Certification is the process by which a non-governmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Registration is the process of making a list or being enrolled in an existing list; registration should be used to help safeguard the public through interstate and intrastate tracking of the technician work force and preventing individuals with documented problems from serving as pharmacy technicians.)

This policy supersedes ASHP policy 0412.

Regulation of Telepharmacy Services (0716)

Source: Council on Public Policy

To advocate that boards of pharmacy adopt regulations that enable the use of United States-based telepharmacy services for all practice settings; further,

To advocate that boards of pharmacy consider the following when drafting regulations for telepharmacy services: (1) education and training of participating pharmacists and technicians; (2) information system requirements; (3) remote order entry, remote prospective order review, remote double-checking of the completed medication order before dispensing, actual dispensing, and patient counseling and education; (4) licensure (including reciprocity) of participating pharmacies and pharmacists; (5) service arrangements that cross state borders; (6) service arrangements within the same corporate entity or between different corporate entities; (7) service arrangements for workload relief in the point-of-care pharmacy during peak periods; and (8) pharmacist access to minimum required elements of patient information; further,

To acknowledge the need to explore and resolve additional legal and professional issues in the provision of international telepharmacy services from sites not located in the United States.

FDA Authority to Prohibit Reuse of Brand Names (0719)

Source: Council on Public Policy

To advocate for Food and Drug Administration authority to prohibit reuse of brand names of prescription and nonprescription drugs when any active component of the product is changed or after any other changes are made in the product that may affect its safe use.

This policy supersedes ASHP policy 0613.

Removal of Propoxyphene from the Market (0723)

Source: Council on Therapeutics

To advocate that the Food and Drug Administration remove propoxyphene from the market because of its poor efficacy and poor safety profile and because more effective and safer alternatives are available to treat mild to moderate pain.

Minimum Effective Doses (0602)

Source: Commission on Therapeutics

To advocate that the Food and Drug Administration require manufacturers to identify minimum effective doses for medications and make this information available to health care providers.

Streamlined Licensure Reciprocity (0612)

Source: Council on Legal and Public Affairs

To advocate that state boards of pharmacy grant temporary licensure to pharmacists who are relocating from another

state in which they hold a license in good standing, permitting them to engage in practice while their application for licensure reciprocity is being processed; further,

To advocate that the National Association of Boards of Pharmacy collaborate with state boards of pharmacy to streamline the licensure reciprocity process.

Accessibility and Affordability of Pharmaceuticals (0506)

Source: Council on Administrative Affairs

To advocate legislation or regulation that would expand eligibility for federal discount drug-pricing programs (e.g., the 340B program) to inpatient drugs for disproportionate-share hospitals; further,

To advocate administrative simplification of existing and any future federal discount drug-pricing programs with respect to qualification and implementation.

Full Health Insurance Coverage (0512)

Source: Council on Legal and Public Affairs

To advocate full health insurance coverage for all persons living in the United States, including coverage of prescription medications and related pharmacist patient-care services; further,

To advocate that all health insurers, both public and private, use the full range of available methods to (1) ensure the provision of appropriate, safe, and cost-effective health care services for their beneficiaries, (2) optimize the treatment outcomes of the insured population, and (3) minimize overall program costs; further,

To advocate that health insurers seek to optimize continuity of care in their design of benefit plans.

Postmarketing Comparative Clinical Studies (0513)

Source: Council on Legal and Public Affairs

To advocate an expansion of comparative clinical studies of the effectiveness and safety of marketed medications in order to improve therapeutic outcomes and promote cost-effective medication use; further,

To advocate that such studies compare a particular medication with (as appropriate) other medications, medical devices, or procedures used to treat specific diseases; further,

To advocate adequate funding for the Agency for Healthcare Research and Quality to carry out such studies; further,

To encourage impartial private sector entities to also conduct such studies.

Premarketing Comparative Clinical Studies (0514)

Source: Council on Legal and Public Affairs

To advocate that the Food and Drug Administration (FDA) have the flexibility to decrease the requirement for placebo-controlled studies, and correspondingly impose a requirement for comparative clinical trials, as more new drug applications are filed for products in the same drug class.

Postmarketing Safety Studies (0515)

Source: Council on Legal and Public Affairs

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA to fulfill this expanded mission related to postmarketing surveillance.

Mandatory Registry of Clinical Trials (0516)

Source: Council on Legal and Public Affairs

To advocate disclosure of the most complete information on the safety and efficacy of drug products; further,

To advocate that the Department of Health and Human Services establish a mandatory registry for all Phase II, III, and IV clinical trials that are conducted on drugs intended for use in the United States; further,

To advocate that each clinical trial have a unique identifier; further,

To advocate that all data from registered clinical trials be posted electronically with unrestricted access, and that such posting occur (1) after Food and Drug Administration approval of the related new product but before marketing begins and (2) as soon as possible for trials completed after initial marketing.

Funding, Expertise, and Oversight of State Boards of Pharmacy (0518)

Source: Council on Legal and Public Affairs

To advocate appropriate oversight of pharmacy practice (including nontraditional practice) and the pharmaceutical supply chain by state boards of pharmacy and other state agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists who are knowledgeable about hospitals and health systems to ensure appropriate oversight of hospital and health-system pharmacy practice; further,

To advocate adequate funding for state boards of pharmacy and related agencies to ensure the effective oversight and regulation of pharmacy practice and the pharmaceutical supply chain.

Compounding by Health Professionals (0411)

Source: Council on Legal and Public Affairs

To advocate the adoption, in all applicable state laws and regulations governing health care practice, of the intent of the requirements and the outcomes for patient safety as described in *United States Pharmacopeia* Chapter 797 (“Pharmaceutical Compounding—Sterile Preparations”).

This policy was reviewed in 2008 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Importation of Pharmaceuticals (0413)

Source: Council on Legal and Public Affairs

To advocate for the continuation and application of laws and regulations enforced by the Food and Drug Administration and state boards of pharmacy with respect to the importation of pharmaceuticals in order to (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States; (2) provide for continued patient access to pharmacist review of all medications and preserve the patient-pharmacist-prescriber relationship; and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications; further,

To urge the FDA and state boards of pharmacy to vigorously enforce federal and state laws in relation to importation of pharmaceuticals by individuals, distributors (including wholesalers), and pharmacies that bypass a safe and secure regulatory framework.

This policy was reviewed in 2008 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Drug Product Shortages (0319)

Source: Council on Legal and Public Affairs

To strongly encourage the Food and Drug Administration to consider, in its definition of “medically necessary” drug products, the impact of medication-use factors, taking into account that if an unfamiliar product is introduced in a clinical setting because the customary product is unavailable, there is increased risk to patient safety; further,

To support government-sponsored incentives for manufacturers to maintain an adequate supply of medically necessary pharmaceutical products; further,

To advocate laws and regulations that would (1) require pharmaceutical manufacturers to notify the appropriate government body at least 12 months in advance of voluntarily discontinuing a medically necessary product, (2) provide effective sanctions for manufacturers that do not comply with this mandate, and (3) require prompt public disclosure of a notification to voluntarily discontinue a medically necessary product; further,

To encourage the appropriate government body to seek the cooperation of manufacturers in maintaining the supply of a medically necessary product after being informed of a voluntary decision to discontinue that product.

This policy was reviewed in 2007 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Greater Access to Less Expensive Generic Drugs (0222)

Source: Council on Legal and Public Affairs

To support legislation and regulations that promote greater patient access to less expensive generic drug products.

This policy was reviewed in 2006 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

FDA’s Public Health Mission (0012)

Source: Council on Legal and Public Affairs

To support the Food and Drug Administration’s public health mission of ensuring the safety and effectiveness of drugs,

biologics, and medical devices through risk assessment, appropriate product approval, labeling approval, manufacturing oversight, and consultation with health professionals, while deferring to state regulation and professional self-regulation on matters related to the use of drugs, biologics, and medical devices; further,

To support the allocation of sufficient federal resources to allow FDA to meet its defined public health mission; further,

To support the appointment of practicing pharmacists to FDA advisory committees as one mechanism of ensuring that decisions made by the agency incorporate the unique knowledge of the profession of pharmacy for the further benefit of the patient; further,

To support an ongoing dialogue between FDA and ASHP for the purpose of exploring ways to advocate the best use of FDA-regulated products by consumers and health care professionals.

This policy was reviewed in 2004 by the Council on Legal and Public Affairs and by the Board of Directors and was found to still be appropriate.

Compliance with Governmental Payment Policies (9902)

Source: Council on Administrative Affairs

To encourage pharmacy managers to identify and resolve medication-related billing issues in government health care programs that could cause challenges under fraud and abuse laws; further,

To encourage pharmacy managers to establish an internal audit system for medication-related services, in conjunction with their corporate compliance programs, in order to meet the requirements of government health care payment policies.

This policy was reviewed in 2008 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Generic Pharmaceutical Testing (9010)

Source: House of Delegates Resolution

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.

This policy was reviewed in 2004 by the House of Delegates and was found to still be appropriate.