

# Government, Law, and Regulation

## 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.*

## Medicare Prescription Drug Benefit (0721)

*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 based on transparency of drug costs; (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 0410.*

## Pharmaceutical Product and Supply Chain Integrity (0722)

*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, 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) accurately document at any point in the distribution chain the original source of drug products and chain of custody from the manufacturer to the pharmacy; 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 0321.*

## 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.

#### **Approval of Generic Biologic Medications (0519)**

*Source: Council on Legal and Public Affairs*

To encourage the development of safe and effective generic versions of biologic medications in order to make such medications more affordable; further,

To encourage research on scientific methods to ensure the safety, effectiveness, and therapeutic equivalence of generic biologic medications; further,

To support legislation and regulation to allow Food and Drug Administration approval of generic versions of biologic medications.

#### **Federal Review of Anticompetitive Practices by Drug Product Manufacturers (0520)**

*Source: Council on Legal and Public Affairs*

To encourage appropriate federal review of the consolidation of the manufacturers of multisource drug products and other potentially anticompetitive practices by manufacturers that adversely affect drug product availability and price.

#### **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”).

#### **Uniform State Laws and Regulations Regarding Pharmacy Technicians (0412)**

*Source: Council on Legal and Public Affairs*

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 a nationally accredited standardized program of education and

training as a prerequisite to pharmacy technician certification; and (3) mandatory certification by the Pharmacy Technician Certification Board (or another comparable nationally validated, psychometrically sound certification program approved by the state board of pharmacy) 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 a nationally accredited standardized 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 nongovernmental 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 0322.*

### **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 supersedes ASHP policy 0320.*

### **Dietary Supplements Containing Ephedrine Alkaloids (0302)**

*Source: Commission on Therapeutics*

To support a ban on the manufacture and sale of dietary supplements containing ephedrine alkaloids because (1) ephedrine alkaloids pose a significant risk of illness and injury, (2) changes in product labeling are not adequate to protect the public from these dangers, (3) the use of these products represents significant expenditures for a health-

related remedy of unsubstantiated value, and (4) other safe and effective interventions are available for all common uses of these products.

### **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 supersedes ASHP policy 0221.*

### **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 2003 by the Council on Administrative Affairs 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.*