

Marketing

Direct-to-Consumer Advertising of Prescription and Nonprescription Medications (1119)

Source: Council on Public Policy

To oppose direct-to-consumer advertising unless it is educational in nature about prescription drug therapies for certain medical conditions and appropriately includes pharmacists as a source of information; further,

To oppose direct-to-consumer advertising of specific prescription drug products unless the following requirements are met: (1) that such advertising is delayed until postmarketing surveillance data are collected and assessed, (2) that the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population, (3) that such advertising promotes medication safety and allows informed decisions, (4) that a clear relationship between the medication and the disease state is presented, (5) that no such advertising or marketing information for prescription or nonprescription medication is directed toward minors, and (6) that such advertising include mechanisms that direct consumers to a medication adverse event reporting system (AERS); further,

To advocate that the Food and Drug Administration require an AERS reporting link in direct-to-consumer advertising material available on the Internet; further,

To support the development of legislation or regulation that would require nonprescription drug advertising to state prominently the benefits and risks associated with product use that should be discussed with the consumer's pharmacist or physician.

This policy supersedes ASHP policy 0609.

Regulation of Off-label Promotion and Marketing (1120)

Source: Council on Public Policy

To advocate for authority for the Food and Drug Administration to regulate the promotion and dissemination of information about off-label uses of medications by manufacturers; further,

To advocate that such promotion and dissemination be permitted only if manufacturers submit a supplemental new drug application for new use within a reasonable time after initial dissemination of information about off-label uses.

Pharmaceutical Distribution Systems (1016)

Source: Council on Pharmacy Management

To support wholesaler/distribution business models that meet the requirements of hospitals and health systems with respect to timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs.

This policy supersedes ASHP policy 0605.

Restricted Drug Distribution (0714)

Source: Council on Public Policy

To affirm support for the current system of drug distribution in which prescribers and pharmacists exercise their professional responsibilities on behalf of patients; further,

To acknowledge that there may be limited circumstances in which constraints on the traditional drug distribution system may be appropriate if the following principles are met: (1) the requirements do not interfere with the continuity of care for the patient; (2) the requirements preserve the pharmacist-patient relationship; (3) the requirements are based on scientific evidence fully disclosed and evaluated by prescribers, pharmacists, and others; (4) there is scientific consensus that the requirements are necessary and represent the least restrictive means to achieve safe and effective patient care; (5) the costs of the product and any associated product or services are identified for purposes of reimbursement, mechanisms are provided to compensate providers for special services, and duplicative costs are avoided; (6) all requirements are stated in functional, objective terms so that any provider who meets the criteria may participate in the care of patients; and (7) the requirements do not interfere with the professional practice of pharmacists, prescribers, and others; further,

To advocate that the Food and Drug Administration (FDA) be granted the authority to consult with practicing pharmacists and others when the establishment of a restricted distribution system is contemplated for a drug product; further,

To advocate that FDA be granted the authority to require that manufacturers disclose all of the considerations that led to the establishment of a restricted distribution system for a specific product; further,

To advocate that FDA be granted the authority to require that manufacturers include in each restricted distribution system a mechanism that will ensure medication reconciliation and continuity of care as patients transition from one level or site of care to another; further,

To advocate that FDA be granted the authority to require manufacturers to conduct a follow-up assessment of the impact of a restricted drug distribution system.

This policy supersedes ASHP policy 0114.

Medication Management for Patient Assistance Programs (0603)

Source: Council on Administrative Affairs

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist-patient relationship.

This policy was reviewed in 2010 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Drug Samples (9702)

Source: Council on Legal and Public Affairs

To oppose drug sampling or similar drug marketing programs that (1) do not provide the elements of pharmaceutical care, (2) result in poor drug control, allowing patients to receive improperly labeled and packaged, deteriorated, outdated, and unrecorded drugs, (3) provide access to prescription drugs by unauthorized, untrained personnel, (4) may encourage inappropriate prescribing habits, or (5) may increase the cost of treatment for all patients.

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.

Manufacturer-Sponsored Patient-Assistance Programs (9703)

Source: Council on Legal and Public Affairs

To encourage pharmaceutical manufacturers to (1) extend their patient assistance programs to serve the needs of both uninsured and underinsured patients, (2) enhance access to and availability of such programs, and (3) incorporate the elements of pharmaceutical care into these programs.

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.