Marketing

Manufacturer-sponsored Patient Assistance Programs (1806)
Source: Council on Pharmacy Management
To advocate that pharmaceutical manufacturers extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients, regardless of distribution channels; further,

To advocate expansion of PAPs to inpatient settings; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance the efficiency of PAPs by standardizing application criteria, processes, and forms; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and visibility of PAPs to pharmacy personnel and other healthcare providers; further,

To encourage pharmacy personnel, other healthcare providers, and pharmaceutical manufacturers to work cooperatively to ensure PAPs include the essential elements of pharmacist patient care, are patient-centered, and are transparent; further,

To develop education for pharmacy personnel and other healthcare providers on the risks and benefits of PAPs.

This policy supersedes ASHP policy 1420.

Restricted Drug Distribution (1714)
Source: Council on Public Policy
To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

This policy supersedes ASHP policy 0714.

Promotion of Off-Label Uses (1620)
Source: Council on Public Policy
To advocate for authority for the Food and Drug Administration (FDA) to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers and their representatives; further,

To advocate that such off-label promotion and marketing be limited to the FDA-regulated dissemination of unbiased, truthful, and scientifically accurate information based on peer-reviewed literature not included in the New Drug Approval process.

This policy supersedes ASHP policy 1120.

Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices (1624)
Source: Council on Public Policy
To advocate that Congress ban direct-to-consumer advertising for prescription drugs and medication-containing devices.

This policy supersedes ASHP policy 1119.

Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs (1521)
Source: Council on Pharmacy Management
To advocate that pharmacists or pharmacy technicians ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist–patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

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 supersedes ASHP policy 0603.

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 2016 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

ASHP Policy Positions 2009–2019 (with Rationales)
Pharmaceutical Industry: Marketing

1806

Manufacturer-sponsored Patient Assistance Programs

Source: Council on Pharmacy Management

To advocate that pharmaceutical manufacturers extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients, regardless of distribution channels; further,

To advocate expansion of PAPs to inpatient settings; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance the efficiency of PAPs by standardizing application criteria, processes, and forms; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and visibility of PAPs to pharmacy personnel and other healthcare providers; further,

To encourage pharmacy personnel, other healthcare providers, and pharmaceutical manufacturers to work cooperatively to ensure PAPs include the essential elements of pharmacist patient care, are patient-centered, and are transparent; further,

To develop education for pharmacy personnel and other healthcare providers on the risks and benefits of PAPs.

This policy supersedes ASHP policy 1420.

Rationale

ASHP recognizes the value of patient assistance programs (PAPs) in improving continuity of care while controlling costs and advocates expanded use of these programs for uninsured and underinsured patients in ambulatory and inpatient care settings. Some organizations have demonstrated success in achieving the benefits of these programs through dedicated resources and a mastery of the many programs available. Simplification of these programs (similar eligibility criteria, a common data format) would reduce the resources required to participate and improve access and utilization. ASHP notes that while the number of PAPs in ambulatory care settings has increased, there has been little growth in programs for inpatients. Hospitals must then absorb the costs of patient care, which results in fewer resources in the overall healthcare system. ASHP believes that expansion of PAPs to indigent inpatients would significantly offset some of the costs to hospitals and ultimately improve care. In addition, interprofessional cooperation will be needed to support patients in accessing drug products when the PAP doesn't cover the cost of the drug product due to high deductibles or co-pays. To ensure that these programs achieve their objectives, ASHP advocates that development of these programs ensure that they contain the elements of pharmacist patient care.

1714

Restricted Drug Distribution

Source: Council on Public Policy

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

This policy supersedes ASHP policy 0714.

Rationale

Restricted drug distribution systems (RDDSes) that are not created solely for patient safety reasons significantly restrict patient access to medications. These systems were justified as a means to closely monitor patient use of medications that could potentially pose a safety risk. They were never intended to allow drug manufacturers to reduce pharmacists' access to medications through limited distribution networks. Using restricted distribution as a tool to gain marketplace advantage rather than for patient safety undermines the justification for such limited systems. ASHP opposes the use of RDDSes for anything other than patient safety and encourages the FDA or other appropriate authorities to investigate whether RDDSes are being used in a manner inconsistent with the original intent. In addition, RDDSes may compromise continuity of care or interfere with pharmacists' accountability for care to certain patient populations, such as when an RDDS prevents a patient's pharmacist from obtaining it. Some investigational drugs approved for marketing under an RDDS are no longer available for qualifying patients on admission through the institution, despite the institution having a history of managing the drug while it was investigational. Such circumstances force the patient to seek care elsewhere or require them and their healthcare providers to unnecessarily utilize additional resources to provide care. In addition, healthcare organizations, responsible for the total care of the patient, including maintaining the patient's medical records, may lose the established patient-care relationship when a patient must go to a specialty pharmacy for a drug the healthcare organization cannot access. RDDSes fragment the healthcare delivery system at a time when public and private payers are increasing incentives to integrate patient care.

1620

Promotion of Off-Label Uses

Source: Council on Public Policy

To advocate for authority for the Food and Drug Administration (FDA) to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers and their representatives; further,

To advocate that such off-label promotion and marketing be limited to the FDA-regulated dissemination of unbiased, truthful, and scientifically accurate information based on peer-reviewed literature not included in the New Drug Approval process.

This policy supersedes ASHP policy 1120.

Rationale

Congress is considering significant changes in the way drugs are developed, approved, and marketed in the United States. A provision in the House-passed 21st Century Cures bill (H.R. 6) would allow pharmaceutical manufacturers to promote off-label uses of their products to clinicians. This change has raised concerns about the accuracy and sources of such information. Sources of such information, if unreliable, could put patient safety at risk. Despite these concerns about promotion of off-label uses by manufacturers, ASHP has suggested an amendment that would require Food and Drug Administration (FDA) oversight of such promotion and require promotional materials to be unbiased, truthful, scientifically accurate, and based upon peer-reviewed literature not included in the approved labeling of the drug. Materials would therefore require approval by the proper authority (FDA), meet certain requirements, and be truthful and scientifically accurate.

1624

Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices

Source: Council on Public Policy

To advocate that Congress ban direct-to-consumer advertising for prescription drugs and medication-containing devices.

This policy supersedes ASHP policy 1119.

Rationale

Direct-to-consumer advertising (DTCA) of prescription drugs and drug-containing implantable medical devices has both positive and negative potential effects. The positive potential effects include broader public awareness and use of therapies, increased patient engagement in their healthcare, and better return on investment in drug and medical device research. These potential benefits need to be weighed against the potential negative effects, however, which include higher drug and device costs, inappropriate prescribing of more costly new drugs or devices without any justifying improvement in patient outcomes, and increased adverse effects. In 2015, the American Medical Association (AMA) adopted a policy calling for a ban on DTCA of prescription drugs and implantable medical devices due to its impacts on drug prices and physician prescribing practices.

Public health researchers have characterized the U.S. experience with direct-to-consumer advertising (DTCA) of prescription drugs since 1997 as "a large and expensive uncontrolled experiment in population health, which to date shows decidedly mixed effects."[1]

[1] Frosch DL, Grande D, Tarn DM, et al. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. *Am J Publ Health* 2010; 100: 24-32. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2791253/ (accessed 2016 Jun 22).

Those researchers and others[2,3,4,5] have identified major impacts of DTCA on public health, including an increase in inappropriate prescribing and adverse effects, medicalization of symptoms previously not defined as illness, and increased costs due to inappropriate prescribing.

The impact of DTCA on the prescriber-patient relationship is hard to quantify. In some surveys, physicians have indicated that they fulfilled questionable DTCA-prompted patient requests for prescriptions.[1] A Food and Drug Administration (FDA) survey the found that "many physicians felt some pressure to prescribe something" when patients mentioned a drug they learned about through DTCA.[2] Studies of claims data support the conclusion that DTCA led to inappropriate prescribing of COX-2 inhibitors and proton pump inhibitors, and experimental evidence suggests that DTCA could induce clinically questionable prescribing of antidepressants for adjustment disorder.[1] Although the connection cannot be proved, it has been suggested that the increasing reliance of physician payments on patient satisfaction surveys could present an economic risk to prescribers who deny patient requests. Studies show that DTCA increases prescribing volume and patient demand, and shifts prescribing.[3] DTCA's effects include overuse of prescription drugs,[4] a shift to less appropriate prescribing,[3] and switches to less cost-effective treatment.[3] In addition, differential effects by patient price sensitivity have been implicated in sustained sales despite a price increase.[3] Researchers have concluded that the overall effects of DTCA on physician–patient communication are unclear,[1] and that the effects of DTCA on improving the quality of care are mixed[1] or lacking in evidence.[3]

The educational value of DTCA has also been questioned. Consumers of DTCA recall more benefit than risk information.[1] Critics of the educational value of DTCA also note that DCTA could exacerbate health disparities due to differing levels of health literacy and lack of incentive to advertise to low-income populations.[1] Researchers have questioned whether purported improvements in adherence, based mainly on negative trials, stand up to scrutiny.[3]

ASHP recognizes that banning a constitutionally protected right to free speech, even commercial speech, must be reinforced by evidence that indicates the banned speech negatively impacts society. In the case of DCTA, those negative impacts, including intrusion on the patient-prescriber relationship and increased healthcare costs, are evident and overwhelming. Given the outsized role prescription drug products have as a cost driver to the healthcare system, the detrimental effects of DCTA, and the limited potential benefits, ASHP has concluded that a ban on DTCA of prescription drugs and drug-containing implantable medical devices is warranted.

1521

IDENTIFICATION OF PRESCRIPTION DRUG COVERAGE AND ELIGIBILITY FOR PATIENT ASSISTANCE PROGRAMS

Source: Council on Pharmacy Management

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[2] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm

[3] Mintzes B. Advertising of prescription-only medicines to the public: Does evidence of benefit counterbalance harm? *Annu Rev Publ Health* 2012; 33: 259-77. DOI: 10.1146/annurev-publhealth-031811-124540.

[4]Donohue JM, Cevasco M, Rosenthal MB. N Engl J Med. 2007; 357:673-81. DOI: 10.1056/NEJMsa070502 Available at www.nejm.org/doi/full/10.1056/NEJMsa070502 (accessed 2016 Jun 22).

[5] Dhaval D, Henry S. Impact of direct-to-consumer advertising on pharmaceutical prices and demand. *Southern Econ J.* 2012; 79: 97–126.

To advocate that pharmacists or pharmacy technicians ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist-patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

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 supersedes ASHP policy 0603.

Rationale

Ensuring patients' medication histories are accurate and continuity of medication therapies is a critical role for pharmacists to monitor and document as patients transition through the healthcare system. Additionally, pharmacists have an important role in ensuring patients have means to access their medications, both upon hospital admission and discharge. With the numerous channels patients use to obtain their medications, it has become increasingly difficult to verify this information and in some cases obtain the medications needed to care for a patient.

Patient assistance programs (PAPs) present a unique challenge for healthcare providers. Documentation of the utilization of a PAP by a patient is important information for providers accessing the patient electronic health record, and improving that documentation should be a priority for healthcare providers. Additionally, pharmacists need to provide leadership in facilitating the utilization of PAPs to ensure continuity of care, the patient's ability to access needed medications when appropriate, and a comprehensive pharmacist-patient relationship.

1016

PHARMACEUTICAL DISTRIBUTION SYSTEMS

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.

Rationale

Wholesaler distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion

of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. ASHP supports wholesaler/distribution business models that meet the requirements of hospitals and health systems.