# Formulary Management

**Pharmacogenomics (1104)**
*Source: Council on Therapeutics*
To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

*This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Medications Derived from Biologic Sources (0809)**
*Source: Council on Pharmacy Practice*
To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of medications derived from biologic sources, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

To facilitate education of pharmacists about the proper use of medications derived from biologic sources.

(*Note:* Section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] defines *biological product* as follows: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine [or any other trivalent organic arsenic compound], applicable to the prevention, treatment, or cure of a disease or condition of human beings.)

*This policy was reviewed in 2012 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Generic Substitution of Narrow Therapeutic Index Drugs (0817)**
*Source: Council on Therapeutics*
To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

To oppose a blanket restriction on generic substitution for any medication or medication class without evidence from well-designed, independent studies that demonstrate inferior efficacy or safety of the generic drug product.

*This policy was reviewed in 2012 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Expression of Therapeutic Purpose of Prescribing (0305)**
*Source: Council on Professional Affairs*
To advocate that the prescriber provide or pharmacists have immediate access to the intended therapeutic purpose of prescribed medications in order to ensure safe and effective medication use.

*This policy was reviewed in 2012 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Appropriate Dosing of Medications in Patient Populations with Unique Needs (0228)**
*Source: Council on Professional Affairs*
To advocate reforms in medication-use systems, including electronic systems, and health care provider education and training that facilitate optimal patient-specific dosing in populations of patients (e.g., pediatrics, geriatrics) with altered pharmacokinetics and pharmacodynamics.

*This policy was reviewed in 2011 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Medication Formulary System Management (0102)**
*Source: Council on Administrative Affairs*
To declare that decisions on the management of a medication formulary system (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, and pharmacoeconomic factors that result in optimal patient care, and (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals; further,

To declare that decisions on the management of a medication formulary system should not be based solely on economic factors.

*This policy was reviewed in 2015 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**Gene Therapy (0103)**
*Source: Council on Administrative Affairs*
To declare that health-system decisions on the selection, use, and management of gene therapy agents should be based on the same principles as a medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, and pharmacoeconomic factors that result in optimal patient care and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals.

*This policy was reviewed in 2015 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**Role of Pharmacists and Business Leaders in Health Care Services and Policies (9819)**
*Source: Council on Professional Affairs*
To support the principle that business leaders and health professionals must share responsibility and accountability for providing optimal health care services to patients; further,

To support the principle that business leaders should expect practicing pharmacists to formulate policies that affect the prerogative of pharmacists to make optimal care decisions on behalf of patients.

*This policy was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Standardization of Drug Medication Formulary Systems (9601)**
*Source: Council on Administrative Affairs*
To support the concept of a standardized medication formulary system among components of integrated health systems when standardization leads to improved patient outcomes; further,

To include in the formulary-standardization process the direct involvement of the health system's physicians, pharmacists, and other appropriate health care professionals.

*This policy was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Medical Devices (9106)**
*Source: Council on Legal and Public Affairs*
To support public and private initiatives to clarify and define the relationship among drugs, devices, and new technologies in order to promote safety and effectiveness as well as better delivery of patient care.

*This policy was reviewed in 2012 by the House of Delegates and by the Board of Directors and was found to still be appropriate.*

**Therapeutic Interchange (8708)**
*Source: Council on Legal and Public Affairs*
To support the concept of therapeutic interchange of various drug products by pharmacists under arrangements where pharmacists and authorized prescribers interrelate on the behalf of patient care.

*This policy was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

# ASHP Policy Positions 2009–2016 (with Rationales): Formulary Management (Medication-Use Policy Development)

**1104**
**PHARMACOGENOMICS**
*Source: Council on Therapeutics*

To advocate that pharmacists take a leadership role in the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy; further,

To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To encourage pharmacist education on the use of pharmacogenomics and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.

*This policy supersedes ASHP policy 0016.*

***Rationale***
The Council reviewed ASHP policy 0016, Pharmacogenomics, as part of a larger discussion on marketing and clinical application of genetic tests available to consumers. The Council voted and the Board and House agreed to amend this policy to more clearly define the role of pharmacists in pharmacogenomic testing.