

POLICY DIGEST

A COLLECTION OF AMCP'S POSITION STATEMENTS ON PROFESSIONAL AND PRACTICE ISSUES

1999-PRESENT





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# **ACADEMY OF MANAGED CARE PHARMACY OVERVIEW**

AMCP's over 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. Pharmacists in managed health care organizations, including health plans and pharmacy benefit managers (PBMs), are responsible for the delivery of prescription drug benefits. It is their responsibility to ensure that the plan they design provides individual patients with appropriate drugs and drug therapies, safely, conveniently and cost-effectively. Managed care pharmacists are committed to ensuring that medications are used appropriately to improve a patient's health.

# **POLICY DIGEST OVERVIEW**

The concise policy statements included in the AMCP Policy Digest are part of an ongoing process that documents the Academy's position on professional and practice issues. The AMCP Policy Digest will serve to aid AMCP members in describing their roles and serves as the basis for AMCP's public policy statements. It aids in advancing AMCP's positions to target audiences. These policy statements, approved by AMCP's Board of Directors, cover a wide range of pharmacy and practice issues and have been derived from existing AMCP Where We Stand Position Statements, Medicare Part D Series, Concept Papers, and other policy statements.

# **POLICY NUMBERING**

Each AMCP policy is assigned an in-house number, consisting of a four-digit code. The first two digits indicate the last two digits of the year in which the policy was introduced; the last two digits indicate sequential numbering for the policy in a given year. The numbering system assists AMCP in tracking and updating the policies and any revisions more efficiently. The number coding can also be used to more efficiently search through the AMCP Policy Digest for policies listed in more than one category.

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# ACCESS TO PATIENT INFORMATION

**Patient Confidentiality** 

Policy 9918

11/01/1999 Introduced 03/01/2001 Revised 06/01/2003 Revised 02/01/2008 Revised 10/01/2012 Reapproved AMCP supports protection of patient confidentiality and endorses the responsible and sensible use of patient identifiable medical and prescription drug information by authorized physicians, pharmacists, other health care professionals, and researchers to enhance the effectiveness and quality of health care service. AMCP believes that state and federal statutes and regulations that pertain to the use of patient identifiable information must not hinder the effective administration of pharmacy benefits and impede patient protections already in place. Managed health care systems should use patient identifiable information only when it is essential to assure or improve safe, accurate and efficient delivery and coordination of health care services.

(See AMCP Where We Stand Position Statement – *Patient Confidentiality*)

Patient Rights and Responsibilities

Policy 9919

11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP recognizes and supports the concept that all consumers should have certain health care rights that assure confidentiality of health care services, provide access to high quality health care, and allow access to information with which they may make informed decisions regarding their health care choices. However, inherent with these rights is the responsibility of each person to implement lifestyle activities that promote optimal responses to health care treatment, to follow medical advice and to become knowledgeable of his or her pharmacy benefit health care options.

(See AMCP Where We Stand Position Statements – *Patient Rights* and *Responsibilities*, and *Patient Confidentiality*)

Electronic Pharmacy Data Processes

Policy 0011

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP supports the use of national standards for: the electronic transfer of patient medical data, particularly electronic pharmacy claims submissions; the electronic transmission of prescription information; the integrity and accuracy of information systems; the electronic and practical processes for drug use evaluation; and the maintenance of the privacy of electronically transferred patient identifiable health information.

Pharmacist Access to Patient Information

Policy 0017

AMCP supports the right of pharmacists in all practice environments to have access to patient identifiable medical and pharmacy information necessary for use in treatment, payment and health care operations to achieve optimal therapeutic outcomes.

02/01/2000 Introduced

02/01/2005 Revised	
11/01/2009 Reapproved	
Pharmacy CPT Codes	AMCP supports the use and expansion of pharmacy-specific codes listed in the American Medical Association's Physicians' Current
Policy 0022	Procedural Terminology (CPT) coding structure to assist pharmacists in coding for their professional services.
02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/01/2014 Reapproved	
Policy Collaboration to Achieve Optimal Patient Outcomes Policy 0023 02/01/2000 Introduced	AMCP supports collaboration with other pharmacy, health care, and consumer organizations in public and professional policy development where such policy development promotes improved patient outcomes and quality of care.
02/01/2005 Reapproved 11/01/2009 Reapproved	
Electronic Exchange of e- Prescribing Information	AMCP supports federal and state legislative provisions that require the electronic transmission of prescriptions between the prescriber to the pharmacist and supports allowing managed health care
Policy 0114  11/01/2001 Introduced 02/01/2005 Revised 11/01/2009 Revised 04/23/2018 Revised	systems to have access to that electronic transmission for appropriate purposes. The Academy believes that the electronic exchange of prescription, drug benefit, and drug information improves patient drug therapy, enhances the collection and analysis of patient data, increases operational efficiencies and optimizes health care outcomes and will decrease abuse and diversion of prescriptions for controlled substances. AMCP will support a limited number of exceptions to mandatory e-prescribing, such as technological or electrical failures, during times of national emergencies and similar circumstances that are beyond the control of prescribers and pharmacies.
National Health Information Network	AMCP supports the development and adoption of a national health information network and recommends that this network include a patient's prescription drug record. This network will be
Policy 0504	instrumental in improving patient outcomes and quality of care.
10/01/2005 Introduced 11/01/2009 Reapproved	
Electronic Health Information Technology	AMCP supports the implementation and expanded use of electronic health information technology, including electronic health records and electronic prescribing, provided that there are appropriate
Policy 0704	mechanisms in place to protect the privacy of patients. Electronic health information technology promises improvement in quality and

02/01/2008 Introduced 10/01/2012 Reapproved

efficiency, data collection and reporting and may help restrain cost increases. Use of this technology will require national standards ensuring patient privacy and system interoperability that are developed in concert with the federal government and patient, provider and payer groups.

(See AMCP Where We Stand Position Statement – *Electronic Health Information Technology*)

AMCP supports the use of prescription information, whether

Appropriate Uses of Prescription Information by Managed Care Organizations

Policy 0903

06/01/2009 Introduced

individually identifiable by patient or prescriber or aggregated without identifying specific individuals, in a responsible manner. When used properly, this information can help promote responsible prescription drug use, protect patient safety and reduce overall health care costs. However, AMCP does not support the use, sale or purchase of this information with the intent to use it for marketing or other commercial purposes.

Transparency Within Health Care

Policy 1104

06/01/2011

(See AMCP Where We Stand Position Statement – Appropriate Uses of Prescription Information by Managed Care Organizations)

Appropriate transparency throughout the health care delivery system can help all parties involved – managed care organizations, payers, providers, and patients – make informed decisions regarding the use of valuable health care resources. These decisions can help promote positive health outcomes protect patient safety and ensure the affordability of a prescription drug benefit. While certain information should remain confidential in order to ensure a competitive marketplace, AMCP supports efforts to promote transparency throughout the entire health care system.

(See AMCP Where We Stand Position Statement – *Transparency Within Health Care*)

Use of Technology

Policy 1307

02/01/2013 Introduced

The Academy of Managed Care Pharmacy (AMCP) supports the implementation and expanded use of health information technology (HIT), including electronic health records and electronic prescribing. AMCP also supports the use of technology in the dispensing and delivery of prescription drugs to patients. AMCP supports the adoption and use of national standards that promote system interoperability among providers and *payers* and the use of requisite sets of functional elements necessary for optimizing medication access, safety and cost-effective utilization.

(See AMCP Where We Stand Position Statement – *Use of Technology in the Health Care System*)

# **AUDIT**

**Audits of Pharmacy Providers** 

Policy 1103

12/01/2011 Introduced 10/01/2012 Reapproved Audits serve two main purposes: 1) detecting fraud, waste and abuse, and 2) validating data entry and documentation to ensure they meet regulatory and contractual requirements. The audit process should be transparent and have a fair design and implementation. The managed care organization should supply the pharmacy provider with a document that defines the requirements on which it may base an audit. The actual audits should be conducted in a manner that leads to continuous quality improvement of the services of the provider, rather than as a source of revenue. Further, the provider must review and be comfortable with these documents before it agrees to a contract. It is imperative that pharmacists-in-charge, and their staff, understand the dispensing and billing requirements and the implications of noncompliance. A bilateral professional level of performance can make the audit process run smoothly, be educational and improve quality.

(See AMCP Model Audit Guidelines for Pharmacy Claims).

# **COLLABORATIVE PRACTICE**

Collaborative Drug Therapy Management

Policy 9903

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 06/01/2011 Revised 10/01/2012 Reapproved AMCP supports the concept of collaborative drug therapy management (CDTM) a formal partnership between a pharmacist and a prescriber that allows the pharmacist to manage a patient's drug therapy. CDTM, also referred to a collaborative practice, allows pharmacists to use their unique skills and abilities to complement other types of care provided by collaborating professionals to optimize patient outcomes. When pharmacists practice under CDTM agreements, equivalent or superior levels of health care services and outcomes are demonstrated when compared with settings where pharmacists were not involved.

(See AMCP Where We Stand Position Statement – *Collaborative Drug Therapy Management*)

# Disease Management

Policy 9907

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Revised 02/21/2018 Revised AMCP supports disease management as the concept of reducing health care costs, closing gaps in care, and improving quality of life for individuals with chronic conditions by preventing or minimizing the effects of the disease through integrated medical and pharmacy management. Disease management programs are designed to improve health outcomes and reduce associated costs from avoidable complications and medication adverse events by identifying and treating chronic conditions more quickly and effectively, and improving appropriate medication use and adherence, thus slowing the progression of those diseases. AMCP recognizes that, as a trained medication management specialist, the pharmacist has clinical expertise and a leadership role to play in the collaborative development, implementation and improvement of disease management programs.

(See AMCP Concepts in Managed Care Pharmacy – *Disease Management*)

### **Formularies**

Policy 9910

11/01/1999 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 02/08/2017 Revised 04/23/2018 Revised AMCP supports the use of appropriately designed formularies as quality-enhancing, cost-effective pharmaceutical care tools that assist members of the health care team in effectively managing a patient's total medical care regimen. A formulary enhances quality of care by encouraging the use of those prescription medications that are demonstrated to be safe, cost effective, with the highest probability of leading to positive patient outcome. To this end, formulary decisions are based primarily on sound clinical evidence. Cost considerations should influence decisions only after safety, efficacy and therapeutic need have been assessed. A formulary works best when it supports and operates in conjunction with other tools that promote quality and optimal results, such as drug utilization review and medical treatment guidelines. In addition, the value of a formulary is maximized when it is part of an integrated patient care continuum, which encourages physicians, pharmacists,

and other care givers to work together to ensure positive outcomes and cost effective results. (See AMCP Where We Stand Position Statement - Formularies, and AMCP Concepts in Managed Care Pharmacy - Formulary Management) Pharmacist's Role in AMCP recognizes that pharmacists have a responsibility to the **Immunizations** public and to individual patients to promote disease prevention through their involvement in community and employer-based Policy 9923 programs that promote appropriate immunization to all citizens, especially those at risk. AMCP supports federal and state legislative 11/01/1999 Introduced and regulatory provisions that give pharmacists the authority to 03/01/2001 Revised administer immunizations. Further, AMCP affirms that schools and 02/01/2006 Reapproved colleges of pharmacy should include education and training 10/01/2010 Reapproved concerning the promotion and administration of immunizations in their curricula. **Evidence-based Clinical Practice** AMCP advocates direct involvement of pharmacists in the Guidelines development, evaluation, and implementation of evidence-based clinical practice guidelines that focus on an interdisciplinary team Policy 0007 approach to patient care. 02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/21/2018 Revised Health Care Team Approach to AMCP believes that achieving optimal therapeutic outcomes for **Optimal Therapeutic Outcomes** each patient is a shared responsibility of the health care team. AMCP further supports the active role of the pharmacist in the Policy 0014 development, implementation and monitoring of therapeutic plans, which include provider communication and assisting patients to 02/01/2000 Introduced become informed decision makers to improve adherence with their 02/01/2005 Reapproved prescribed therapeutic plan. 02/01/2010 Reapproved 04/07/2015 Revised State Pharmacy Practice Act AMCP recommends enactment of state pharmacy practice act Revisions revisions enabling pharmacists to fulfill their roles as health care providers, drug therapy managers, and full members of the patient Policy 0026 care team. 02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved

### Pharmacogenomics

Policy 0107

03/01/2001 Introduced 11/01/2005 Reapproved 11/01/2009 Revised 02/01/2014 Revised AMCP supports further research and assessment of the economic, clinical, and humanistic impact of pharmacogenomics on managed care pharmacy practice. AMCP supports the pharmacist's leadership role in the review and evaluation of scientific evidence and the subsequent development of pharmaceutical care processes involving these therapies through collaboration with other health care practitioners and consumer organizations. Pharmacy and Therapeutics Committees in collaboration with Health Technology Assessment committees should be involved in the decision-making process related to coverage of genetic tests and utilization management strategies.

Pharmacy Benefits for the Uninsured/Underinsured

AMCP supports the development of systems to ensure access to pharmacists and pharmaceuticals for all patients, regardless of income or insured status.

Policy 0118

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Reapproved

Continuous Quality Improvement

Policy 0301

02/01/2003 Introduced 02/01/2008 Reapproved 10/01/2012 Reapproved 02/21/2018 Revised AMCP supports development and implementation of continuous quality improvement programs throughout the medication use process, and encourages all practitioners to establish performance improvement processes in their various practice settings.

**Utilization Management** 

Policy 0401

02/01/2004 Introduced 12/01/2008 Reapproved 10/01/2012 Revised AMCP supports the role of utilization management in the provision of quality, cost-effective prescription drug benefits. The fundamental goal of utilization management is to promote the appropriate and cost-effective use of medications. Pharmacists in all practice settings must work collaboratively to develop specific policies and procedures to ensure that the utilization management process is administered in the most efficient manner possible, is fully compliant with statutory and regulatory requirements and provides members, pharmacists and prescribers with an evidence-based, rational process to promote appropriate drug use. Examples of utilization management strategies used within a prescription drug benefit include prior authorization, step therapy, quantity management, and the formulary exception process.

(See AMCP Concepts in Managed Care Pharmacy – *Prior Authorization*)

Patient Care Services Provided by a Pharmacist

(Prior to 7/29/14 revision, titled: Compensation for Pharmaceutical Care Services)

Policy 0601

02/01/2006 Introduced 12/01/2010 Revised 07/29/2014 Revised

Medication
Reconciliation/Transitions of
Care

Policy 0702

04/01/2007 Introduced

Medication Therapy
Management (MTM) Programs

Policy 0906

06/01/2009 Introduced 02/01/2014 Revised

AMCP believes that the pharmacist and health care practitioners, as the medication management professional, has the training and expertise to provide pharmaceutical care services that improve patient outcomes and reduce health care costs. AMCP encourages pharmacists to lead collaborative efforts in the development and implementation of pharmaceutical care plans. AMCP supports adequate compensation for pharmaceutical care services provided by pharmacists or other licensed health care providers that demonstrate value to practitioners, patients and payers.

AMCP supports pharmacists in their unique role in ensuring the continuity of a patient's medication therapy regimen when moving among diverse health care settings. Pharmacists analyze and communicate information about the safety, effectiveness and outcomes of drug therapy to other health care providers to ensure appropriate continuity of drug therapy. Additionally, pharmacists can best serve patients by providing consultation that gives them the ability to understand and remain adherent to medication therapy regimens as the patient moves from one setting to another.

(See AMCP Framework for Quality Drug Therapy)

AMCP recommends that medication therapy management (MTM) programs be designed based on the needs of identified populations of a plan, utilizing appropriate patient selection criteria and interventions to meet the needs of individual members and optimize medication use. Emphasis should be placed on coordination of care for the patient, and integration of MTM programs, disease management and medical management programs, when possible, to effectuate enhanced patient outcomes. MTM programs should identify appropriate outcomes and design measurements to assess the outcomes while maintaining appropriate documentation and results. MTM programs should be evaluated and revised on a continuing basis to ensure that appropriate quality and continued value is maintained.

**Provider Status for Pharmacists** 

Policy 1201

06/01/2013 Introduced 03/27/2017 Revised 07/19/2018 Revised 10/22/2018 Revised The Academy of Managed Care Pharmacy (AMCP) supports the recognition of pharmacists as providers under the Social Security Act. Pharmacists provide measurable improvements in healthcare outcomes and patientsatisfaction and reduce overall healthcare expenditures. AMCP strongly believes the formal recognition of pharmacists as health care providers will increase their contribution to address primary healthcare needs, including medication administration, as part of collaborative healthcare with fewer barriers.

(See AMCP Where We Stand Position Statement – *Provider Status for Pharmacists*)

Therapeutic Interchange

Policy 9928

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Revised AMCP supports the use of evidence-based therapeutic interchange programs as a part of a comprehensive approach to quality, costeffective patient care. AMCP believes that therapeutic interchange represents an efficient use of medical resources that helps keep medical costs down, improves the patient's access to more affordable health care, and enhances the patient's quality of life. The programs are designed to work in conjunction with other tools that health care professionals use to promote quality medical outcomes, add value, and increase affordability to patients and payers. Therapeutic interchange is not always about lower drug costs, however. Frequently, therapeutic interchange occurs when overall health care savings can be achieved. In some instances, replacing one drug with a more expensive drug may result in fewer treatment failures, better patient adherence to the treatment plan, fewer side effects, and improved clinical outcomes.

(See AMCP Where We Stand Position Statement – *Therapeutic Interchange*).

**Emergency Preparedness** 

Policy 0303

11/01/2003 Introduced 02/01/2008 Revised 10/01/2012 Revised AMCP recognizes that pharmacists play a vital role in maintaining and promoting public health. Therefore, AMCP supports continuing efforts of the Joint Commission of Pharmacy Practitioners, the state boards of pharmacy, state and federal governments and/or military agencies to ensure national emergency preparedness. AMCP also encourages pharmacists to participate on National Disaster Medical Assistance Teams and to serve on local units of Medical Reserve Corp for responding to national and local emergencies.

Medication Synchronization

Policy 1501

02/10/2015 Introduced

The Academy of Managed Care Pharmacy (AMCP) supports the concept of medication synchronization as one tool that may improve adherence. Prescription drug therapy provides a tremendous value to the overall healthcare system and that value is only realized when medication therapies are taken by patients as prescribed. AMCP supports continued industry development and rollout of medication synchronization programs and believes that best practices currently being developed will benefit patients and payers. Therefore AMCP will oppose legislation that mandates

medication synchronization and requires a specific government framework as an unnecessary barrier to best practices.

(See AMCP Where We Stand Position Statement – *Medication Synchronization*.)

# **COMPOUNDING**

**Compounding of Drug Products** 

Policy 0005

02/01/2000 Introduced 06/01/2005 Revised 11/01/2009 Reapproved 02/01/2014 Revised AMCP recognizes that preparation of compounding products pursuant to or in anticipation of a prescription, which is intended to meet the specific needs of an individual patient when those needs are not met by a commercially available product is an important part of pharmacy practice. AMCP supports good manufacturing practices in accordance with FDA policies and regulatory oversight.

# **DISPENSING**

DISPLINSING	
Application of Dispensing Criteria to All Providers	AMCP supports legislative and regulatory standards that require any health care provider empowered to dispense or furnish prescription and/or non-prescription drugs to be equally subject to all state and federal laws and regulations concerning these functions
Policy 0001	federal laws and regulations concerning these functions.
02/01/2000 Introduced	
02/01/2005 Reapproved	
11/01/2009 Reapproved 02/21/2018 Reapproved	
Therapeutic Purpose Inclusion	AMCP encourages the inclusion of the therapeutic purpose on all
on Prescriptions and Medication Orders	prescriptions and medication orders.
Policy 0027	
11/01/1999 Introduced	
03/01/2004 Reapproved	
12/01/2008 Reapproved	
10/01/2012 Revised 03/27/2017 Reapproved	
Pharmacist Responsibility in the	AMCP supports the pharmacist's authority to control and direct the
Drug Distribution Process	drug distribution process and the requirement that the pharmacist bear responsibility for all completed medication orders regardless
Policy 0028	of practice setting.
02/01/2000 Introduced	
02/01/2005 Reapproved	
02/01/2010 Reapproved 04/07/2015 Reapproved	
04/07/2013 Кеарргочей	
Redispensing of Unused	AMCP supports programs for the return, reuse and payment credit
Medications	of unused medications from state programs, long-term care
Dollar 0702	facilities, and other medical facilities.
Policy 0703	Authority to redispense medication should only be permitted
06/01/2007 Introduced	when:
	<ul> <li>Unused medication has not left the supervision of a health</li> </ul>
	care professional or designated representative
	Unused medication is in the original sealed packaging
	(e.g., unit of use packaging)
	<ul><li>Unused medication has been properly stored</li><li>Unused medication has not expired</li></ul>
	Onused medication has not expired
	In addition, such programs should:
	<ul> <li>Provide an equal standard of care for all patients</li> </ul>
	Decrease waste

- Decrease medication costs for both patient and benefit providers
- Minimize environmental impact of discarded medication
- Ensure the integrity and safety of the product
- Protect the privacy of the original recipient
- Comply with state and federal requirements

Behind-the-Counter Drugs

Policy 0903

06/01/2009 Introduced

AMCP supports the establishment of a class of drugs that would allow consumers, with the intervention of a pharmacist, to purchase certain medications without a prescription. The establishment of a behind-the-counter (BTC) classification would grant patients access to necessary medications while being counseled by a pharmacist to ensure that the patient meets certain criteria prior to dispensing and to provide education on proper use and monitoring. AMCP supports the establishment of a third class of BTC drugs if the following conditions are met:

- Medications selected for BTC status must provide a benefit to the public
- Decisions on which drugs are selected for BTC status must be based on clinical effectiveness and safety
- Standardized processes for ordering and dispensing of BTC drugs must be established
- Pharmacists must be required to perform clinical evaluation and interventions before dispensing BTC drugs
- Pharmacist training requirements must be based on knowledge and skills required to interpret objective clinical data and to apply selection criteria in order to dispense BTC products
- Patient health information must be protected
- Program oversight requirements must be developed

(See AMCP Where We Stand Position Statement – *Behind-the-Counter Drugs*)

**Audits of Pharmacy Providers** 

Policy 1103

12/01/2011 Introduced 10/01/2012 Reapproved Audits serve two main purposes: 1) detecting fraud, waste and abuse, and 2) validating data entry and documentation to ensure they meet regulatory and contractual requirements. The audit process should be transparent and have a fair design and implementation. The managed care organization should supply the pharmacy provider with a document that defines the requirements on which it may base an audit. The actual audits should be conducted in a manner that leads to continuous quality improvement of the services of the provider, rather than as a source of revenue. Further, the provider must review and be comfortable with these documents before it agrees to a contract. It is imperative that pharmacists-in-charge, and their staff, understand the dispensing and billing requirements and the implications of non-

compliance. A bilateral professional level of performance can make the audit process run smoothly, be educational and improve quality.

(See AMCP Model Audit Guidelines for Pharmacy Claims)

medication access, safety and cost-effective utilization.

Use of Technology The Academy of Managed Care Pharmacy (AMCP) supports the implementation and expanded use of health information technology (HIT), including electronic health records and electronic prescribing. AMCP also supports the use of technology in the 02/01/2013 Introduced dispensing and delivery of prescription drugs to patients. AMCP supports the adoption and use of national standards that promote system interoperability among providers and payers and the use of requisite sets of functional elements necessary for optimizing

> (See AMCP Where We Stand Position Statement - Use of Technology in the Health Care System)

> The Academy of Managed Care Pharmacy (AMCP) believes that managed care organizations (MCOs) must have the flexibility to use mail service delivery of prescription drugs as a component of their prescription drug benefit. Mail service pharmacies are a valuable

> tool used by MCOs to increase patient safety, offer patient convenience, and maintain the affordability of the prescription drug benefit as a whole. Additionally, MCOs should have the ability to set patient cost-sharing levels for prescription orders filled through mail service pharmacies different from the patient cost-sharing levels for prescription orders filled through retail pharmacies.

> (See AMCP Where We Stand Position Statement – *Mail Service*

Pharmacies)

The Academy of Managed Care Pharmacy (AMCP) supports the Medication Synchronization concept of medication synchronization as one tool that may

> improve adherence. Prescription drug therapy provides a tremendous value to the overall healthcare system and that value is only realized when medication therapies are taken by patients as prescribed. AMCP supports continued industry development and rollout of medication synchronization programs and believes that best practices currently being developed will benefit patients and payers. Therefore AMCP will oppose legislation that mandates

> medication synchronization and requires a specific government framework as an unnecessary barrier to best practices.

> (See AMCP Where We Stand Position Statement – Medication Synchronization.)

Policy 1307

Mail Service Pharmacies

Policy 1202

Policy 1501

02/10/2015 Introduced

12/01/2012 Introduced

AMCP Policy Digest November 2018

# **DRUG CLASSIFICATION**

Prescription to OTC Switches	AMCP supports the Food and Drug Administration's regulatory process that allows over-the-counter (OTC) marketing of a drug
Policy 0108	product that was previously only available by prescription. In determining whether a drug product should be classified as
03/01/2001 Introduced	prescription only or available OTC, AMCP encourages that: (1) a
02/01/2006 Revised	range of stakeholders be included in the evaluation process; (2)
02/01/2011 Revised	procedures to initiate petitions to switch drugs from one status to
02/01/2011 Neviseu	·
	another be available to stakeholders; and (3) stakeholders take an
	active role in the FDA's scientific and clinical evaluation of drugs
	potentially eligible for OTC status.
Abuse Deterrent and Tamper	AMCP encourages the U.S. Food and Drug Administration (FDA) to
Resistant Formulations	use its expertise to establish standards for the definition of "abuse-
	deterrent" and "tamper resistant." The Agency should also require
Policy 1802	that manufacturers of those products undertake reasonable post-
	marketing surveillance studies that will help assess the impact of the
04/23/2018 Introduced	products on both the abuse of the specific product, as well as overall
. , .,	rates of abuse. Because opioids may vary in their clinical
	effectiveness and abuse potential, AMCP supports expanding the
	ability of health plans to clinically manage these products.
	Therefore, AMCP does not support mandating the use of "abuse
	· · · · · · · · · · · · · · · · · · ·
	deterrent" and "tamper resistant products." AMCP maintains that
	such products are not clinically necessary for all patients.

# **DRUG INTEGRITY**

**Drug and Device Recalls** AMCP supports the use of technologies to enhance communication of recall information to all relevant parties including patients who Policy 0009 may have received such products. 02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved **Drug Integrity and Stability** AMCP encourages all entities involved in the distribution of pharmaceutical products to assure that drug product integrity and Policy 0010 stability is maintained throughout the continuum of the drug distribution system. 02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved **Prescription Drug Importation** Legislation that would permit the importation of prescription drugs presents potential patient safety issues. Allowing the importation of Policy 0302 prescription drugs raises a challenge to ensure that quality assurance standards have been maintained. AMCP believes that 02/01/2003 Introduced more conclusive data are needed as to the likely impact of 02/01/2008 Revised importation. AMCP will oppose legislation that would allow the 02/01/2013 Revised importation of prescription drugs for sale in the United States until more conclusive data are available as to its likely impact. (See also AMCP Where We Stand Position Statement – *Prescription* Drug Importation)

# **DRUG NAMING**

Drug Names, Labels, and Packaging

Policy 9908

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Reapproved AMCP encourages drug manufacturers and the FDA to work with pharmacists, physicians, other health care professionals and professional organizations to design and adopt drug names, labeling, and packaging that will avoid confusion and help prevent medication errors.

**OTC Brand Name Confusion** 

Policy 0106

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Reapproved AMCP is concerned that a distinct brand name on an OTC product does not always refer to the same active ingredient(s). This inconsistent relationship between brand name and ingredients may be confusing to some patients and may lead to medication errors and adverse events. AMCP believes that the naming approach should be changed to avoid this confusion. In conjunction with pharmacists, physicians, and other health care professionals, product names and packaging should be adopted and designed to minimize confusion and prevent adverse outcomes.

# **DRUG PRICING**

Direct-to-Consumer Advertising of Prescription Products Policy 9906	AMCP supports direct-to-consumer advertising that educates the public about disease symptoms and available treatment options. AMCP discourages the use of direct-to-consumer advertising that promotes specific prescription drug products.
11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Reapproved	(See AMCP Where We Stand Position Statement – <i>Direct-to-Consumer Advertising of Prescription Products</i> ).
Evidence-based Advertising of Pharmaceuticals  Policy 0012  02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Revised 12/01/2013 Revised	AMCP supports federal regulatory requirements that ensure that prescription and non-prescription advertising to health care practitioners and patients contains claims that are supported by evidence-based research, and that such advertising does not contribute to drug abuse or indiscriminate use of medication.
Best Price Requirements of the Medicaid Drug Rebate Program  Policy 0904  06/01/2009 Introduced	AMCP believes that the best price provisions of the Medicaid prescription drug rebate program, established by the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508), represents interference by the government into the competitive marketplace that has raised costs unnecessarily by preventing the commercial market from allowing true market dynamics to emerge. This pernicious market effect has been well documented by the U.S. Government Accountability Office (GAO), the Congressional Budget Office (CBO) and academic economists. AMCP strongly encourages a careful re-examination of the best price program.  (See AMCP Where We Stand Position Statement – Best Price Requirements of the Medicaid Drug Rebate Program)
Government Regulation of Prescription Drug Prices  Policy 1003  06/01/2010 Introduced	AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care benefits. Government-regulated prices could greatly impair the ability of managed care organizations (MCOs) to design a competitive benefit offering that integrates clinically sound, evidence-based medication choices with delivery systems and copayment alternatives that provide beneficiaries with substantive choice. Legislation that would allow the government to regulate prescription drug prices, though well intentioned, could actually result in increased costs for many consumers in the short term and for all in the long term.

(See AMCP Where We Stand Position Statement – Government Regulation of Prescription Drug Prices)

Maximum Allowable Cost (MAC) Pricing

Policy 1301

10/01/2013 Introduced

AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care Legislation that allows the government to dictate benefits. reimbursement terms of a private contract between a payer and a pharmacy or that mandates that the payer disclose proprietary pricing methodology is not an appropriate focus of government regulation. Further, AMCP believes that competitive negotiations between parties are more likely to provide fair and equitable reimbursement on drugs dispensed. AMCP does not support the intervention of government into private contracts to require payers to advise pharmacies on where to purchase their drugs; that is an unnecessary and inappropriate intrusion into the private arrangements of a pharmacy with its supplier. This type of government mandate takes away the incentive for a pharmacy to make wise purchasing decisions. The payers and consumers will not benefit from a system of government mandated payments to a private entity; rather it will decrease competition and further drive up the cost of the prescription drug benefit.

[See AMCP Where We Stand Position Statement – Government Regulation of Prescription Drug Prices]

Transparency Within Health Care

Policy 1104

06/01/2011

Appropriate transparency throughout the health care delivery system can help all parties involved – managed care organizations, payers, providers, and patients – make informed decisions regarding the use of valuable health care resources. These decisions can help promote positive health outcomes protect patient safety and ensure the affordability of a prescription drug benefit. While certain information should remain confidential in order to ensure a competitive marketplace, AMCP supports efforts to promote transparency throughout the entire health care system.

(See AMCP Where We Stand Position Statement – *Transparency Within Health Care*)

Co-payment Offset Programs AMCP is supportive of programs that help patients afford their prescription drugs. However, some programs can needlessly Policy 1302 encourage the use of more expensive brand-name products over their generic counterparts. They can also undermine the formulary 02/01/2013 Introduced development process by encouraging the use of products that have lower cost therapeutic alternatives. Patient safety can also be threatened when prescriptions are frequently transferred between retail pharmacies. Therefore, AMCP is opposed to manufacturer coupon programs that are promotional in nature and are not means-tested. (See AMCP Where We Stand Position Statement – Co-Payment Offset Program) Government Negotiation of The Academy of Managed Care Pharmacy (AMCP) opposes **Prescription Drug Prices** legislation that would allow or require the federal government to negotiate prescription drug prices on behalf of Medicare Part D Policy 1304 plan sponsors. The Academy supports the current structure of the Part D benefit that relies on the concept that drug price concessions are best achieved by negotiations by participating 02/01/2013 Introduced drug plan sponsors who themselves are motivated by the competitive need to provide the most cost-effective and clinically appropriate drug benefits possible. AMCP believes proposals to repeal the noninterference provision would introduce consequences that must be thoughtfully considered before action is taken. (See AMCP Medicare Part D Concept Series – Government Negotiation of Prescription Drug Prices) The Academy of Managed Care Pharmacy (AMCP) supports the The Competitive Model continuation of the competitive model for the Medicare Part D program. The Academy supports legislation and regulation that Policy 1305 will allow proven private sector best practices to be applied in the public sector. The Academy will oppose changes to the drug 02/01/2013 Introduced benefit program that would undermine the use of effective managed care strategies. It will oppose changes that would dilute the competitive structure currently being used for the delivery of the Medicare drug benefit. Additionally, program elements that hinder the use of pharmacy benefit best practices from the private sector should be eliminated. (See AMCP Medicare Part D Concept Series – The Competitive Model) **Value Based Contracts** AMCP supports the development of value-based contracts (VBCs) as an innovative means of shifting health care payment models from focusing on volume to focusing on value. The shift in payment Policy 1801 models is expanding beyond the delivery of health care services to encompass models of compensation between payers and 04/23/2018 Introduced biopharmaceutical manufacturers. VBCs have emerged as a mechanism that payers may use to better align their contracting

structures with broader changes in the overall health care system. A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures. AMCP is committed to advocating for legislative and regulatory changes when necessary to address barriers to the optimal execution of VBCs.

# **EDUCATION, CURRICULUM, AND TRAINING**

Continuing Competence for Pharmacists

Policy 9905

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Reapproved AMCP supports the collaboration of pharmacists, managed health care systems, employers, payers, professional organizations, and legislative and regulatory organizations in the development of continuous quality improvement mechanisms to assess, ensure, and promote competence of pharmacists. Pharmacists have a responsibility to identify areas for focused education and/or experiential training and to reassess their competence in these areas.

Managed Care Pharmacy Practice Residency Programs

Policy 9913

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/08 Reapproved 10/01/2012 Reapproved

Public Funding for Pharmacy Residency Programs

Policy 9926

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Reapproved 02/21/2018 Reapproved AMCP encourages managed care pharmacy practice residency program directors to seek accreditation under the Accreditation Standard and Learning Objectives for Residency Training in Managed Care Pharmacy Practice jointly prepared by AMCP and ASHP.

AMCP supports legislation and regulation that ensures public funding for pharmacy residency training programs. AMCP opposes legislation and regulation that would reduce reimbursement levels for graduate medical education or would set reimbursement for pharmacy residency programs at a rate disproportionate to other residency programs.

Best Practice Principles  Policy 0002  02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Revised	AMCP supports identifying, recognizing and exchanging best practices in managed care pharmacy in all practice sites. Furthermore AMCP supports the inclusion of best practice principles in mentoring and preceptor programs.
Non-traditional Education  Policy 0016  02/01/2000 Introduced 02/01/2005 Reapproved 02/01/2010 Reapproved 04/07/2015 Reapproved	AMCP encourages colleges of pharmacy to offer non-traditional, post-baccalaureate, pathways to the doctor of pharmacy degree readily accessible to working pharmacists, resulting in graduates who have demonstrated the same competencies as those in entry-level programs.
Pharmacist Educational Advancement  Policy 0019  02/01/2000 Introduced 02/01/2005 Reapproved 02/01/2010 Reapproved 04/07/2015 Reapproved	AMCP encourages schools and colleges of pharmacy to further advance educational requirements to ensure the provision of a balanced, general education, including information regarding emerging technologies and health care systems, in order to graduate educated citizens and competent health care professionals.
Promotion and Certification of Pharmacy-Based Health Management Programs  Policy 0025  02/01/2000 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 04/07/2015 Reapproved	AMCP supports legislation and regulation promoting pharmacy-based health management programs, such as health screenings and immunizations, and additionally, health status monitoring through pharmacist ordering and interpretation of laboratory tests as they may relate to the usage, dosing and administration of drugs. As these activities may encompass skills and abilities beyond the traditional practice of pharmacy, AMCP further supports the completion of a comprehensive instruction program within pharmacy curricula or a post-graduate certificate program to ensure pharmacists are appropriately credentialed to perform such

services.

## **Residency Training**

Policy 0111

03/01/2001 Introduced 02/01/2006 Reapproved 12/01/2010 Revised 04/07/2015 Reapproved AMCP recognizes the importance of residency and fellowship programs in further educating pharmacists in their applicable fields. However, the Academy believes that the market will define what advanced training will be required and that the mandatory requirement of residencies is unnecessary. The Academy believes that clinical expectations of certain organizations (hospitals, managed care organizations) and disciplines will drive the need for advanced training in those areas. Also the need for a competitive advantage may push pharmacists and organizations that employ or contract with pharmacists to require residencies or advanced training. The Academy does not supports professional policies requiring residency training for entry into pharmacy practice.

# **ETHICS**

Code of Ethics for Pharmacists

AMCP endorses the Code of Ethics for Pharmacists.

Policy 9902

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Reapproved (See Code of Ethics for Pharmacists at http://www.pharmacist.com/code-ethics)

Conscientious Objection by Pharmacists to Certain Therapies

Policy 9904

11/01/1999 Introduced 06/01/2005 Reapproved 11/01/2009 Reapproved 02/21/2018 Reapproved Clinical Investigations in

Children

Policy 0003

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/01/2014 Revised AMCP supports a pharmacist's right to refuse to fill a prescription on the basis of the pharmacist's moral, religious, or ethical convictions. While the pharmacist's right of conscientious objection must be respected, managed health care systems must ensure that procedures are established that protect the patient's right to obtain legally prescribed and medically necessary treatments consistent with the benefit coverage provided.

AMCP supports the inclusion of children in clinical investigations of drug products where appropriate safeguards are instituted to ensure the safety of children; where the use of the drug has significant indications (need for use) in children, and where appropriate, there is prior experience with the drug in the adult population.

**Pharmacist Recovery Programs** 

Policy 0021

02/01/2000 Introduced 02/01/2003 Revised 02/01/2008 Revised 10/01/2012 Reapproved AMCP supports the establishment by state boards of pharmacy of counseling, treatment, prevention, and rehabilitation programs for pharmacists, pharmacy technicians and student pharmacists who are subject to physical or mental impairment due to the influence of drugs — including alcohol — or other causes, when such impairment has potential to adversely impact their abilities to function properly in a professional capacity. AMCP supports the empowerment of state boards of pharmacy to use discretionary powers in determining employment waiver requests relating to the licensure of impaired pharmacists and pharmacy technicians.

Professionalism and Professional Judgment

Policy 0024

02/01/2000 Introduced 02/01/2005 Reapproved 02/01/2010 Reapproved 10/07/2014 Reapproved 04/07/2015 Reapproved Cultural Diversity

Policy 0503

10/01/2005 Introduced 11/01/2009 Reapproved Fraud, Waste and Abuse in Prescription Drug Benefit

Policy 1105

10/01/2011

AMCP believes that it is essential to integrate professionalism concepts and standards during a pharmacy student's educational experience and throughout a pharmacist's career. Pharmacists, regardless of practice setting, must possess the requisite competencies to allow them to exercise their individual professional judgment and have complete authority for those individual professional responsibilities assumed.

AMCP supports the awareness of cultural diversity that exists among health care providers and patients. AMCP recognizes the potential impact of cultural diversity related to medication use as well as access to health care. AMCP supports the development of cultural diversity competencies for health care professionals, students, and educators.

### Fraud

- AMCP supports efforts by both federal and state governments that enhance law enforcement's ability to combat the actions of individuals who falsify prescription information or providers who write prescriptions for patients who intend to abuse the drugs.
- AMCP supports efforts to encourage the adoption of electronic prescribing systems, which could reduce the incidence of fraud at the pharmacy point-of-sale.
- AMCP is opposed to requirements that managed care organizations contract with any pharmacy willing to meet the terms and conditions of an organization's contract, also known as "any willing provider" requirements. Without such requirements, a managed care organization may refuse to contract with a pharmacy that is suspected of fraudulent activity, such as a pharmacy that files claims and receives payments for prescriptions that are never filled.

Waste

- AMCP supports exemptions from these laws that would allow a health plan or PBM to suspend payment when there is credible evidence of fraud.
- AMCP supports efforts to make generic substitution an easy process for pharmacists and prescribers.
- AMCP opposes regulations that would unnecessarily place a burden on either party in order to make a substitution.
- AMCP supports allowing managed care organizations the flexibility to design pharmacy benefits that encourage the use of therapeutic treatment options that are most appropriate in terms of both patient outcomes and costs to both the patient and payer.

#### Abuse

- AMCP supports measures to prevent abuse of prescription drugs as well as prescription drug benefit plans.
- AMCP supports programs that gather dispensing information about controlled substances so that the pharmacist has a resource for checking "pharmacy and doctor shopping" patterns.
- AMCP supports sensible changes to current law that would allow Part D plan sponsors to help combat the problem of prescription drug abuse.

(See AMCP Where We Stand Position Statement – Fraud, Waste and Abuse in Prescription Drug Benefits)

### FORMULARY MANAGEMENT

**Drug Use Evaluation** 

Policy 9909

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Reapproved 02/08/2017 Reapproved AMCP recognizes the value of drug use evaluation (DUE) as a means of improving the quality of patient care, enhancing therapeutic outcomes, and reducing inappropriate pharmaceutical expenditures, thus reducing overall health care costs. Using DUE information, managed care pharmacists can identify prescribing trends in patient populations and initiate corrective action to improve drug therapy for groups of patients, as well as individuals.

(See AMCP Concepts in Managed Care Pharmacy – *Drug Use Evaluation*).

### **Formularies**

Policy 9910

11/01/1999 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 02/08/2017 Revised 04/23/2018 Revised AMCP supports the use of appropriately designed formularies as quality-enhancing, cost-effective pharmaceutical care tools that assist members of the health care team in effectively managing a patient's total medical care regimen. A formulary system enhances quality of care by encouraging the use of those prescription medications that are demonstrated to be the safest, most effective, and produce positive patient outcomes. To this end, formulary decisions are based primarily on sound clinical evidence. Cost considerations should influence decisions only after safety, efficacy, and therapeutic need have been assessed. A formulary works best when it supports and operates in conjunction with other tools that promote quality and optimal results such as drug utilization review and medical treatment guidelines. In addition, the value of a formulary is maximized when it is part of an integrated patient care process which encourages physicians, pharmacists, and other care givers to work together to ensure positive outcomes and costeffective

(See AMCP Where We Stand Position Statement – Formularies, and AMCP Concepts in Managed Care Pharmacy – Formulary Management)

Generic Drug Products

Policy 9911

11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Revised 02/01/2014 Revised AMCP encourages pharmacists and managed health care systems to promote the use and benefits of FDA-approved and therapeutically equivalent generic drug products as safe, effective, and costeffective alternatives to brand-name equivalents. AMCP supports legislative and regulatory changes that would promote the development and use of safe, efficacious and equivalent generic drugs and eliminate barriers that can unnecessarily delay the entry of the generic drugs into the marketplace. AMCP believes that Congress must ensure that the FDA has access to adequate resources in order to review and process applications for generic drugs and eliminate unnecessary delays of their approval. AMCP opposes state and federal legislative and regulatory provisions that would restrict the right of pharmacists, in collaboration with

prescribers and patients, to exercise their professional judgment in choosing the most appropriate generic or brand-name equivalent products for patients.

(See AMCP Where We Stand Position Statement – Generic Drugs)

(See also AMCP Where We Stand Position Statement – *Biosimilar Drug Therapies*)

Interchange of Narrow
Therapeutic Index (NTI) Drugs

Policy 9912

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved AMCP supports the Food and Drug Administration's (FDA) position that when an FDA-approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be assured that they will see the same clinical results and safety profile as with the equivalent brand name product. Therefore, NTI drugs should not be considered as a separate category for purposes of generic substitution. AMCP believes that pharmacists, in consultation with prescribers, should have the right to use their professional judgment and knowledge of the available scientific information in determining when to substitute a generic product.

(See AMCP Where We Stand Position Statement – *Interchange of Narrow Therapeutic Index (NTI) Drugs*)

Off-Label Use of Pharmaceuticals

Policy 9916

11/01/1999 Introduced 02/01/2003 Revised 02/01/2008 Reapproved 10/01/2012 Reapproved The Academy of Managed Care Pharmacy supports off-label use of FDA-approved drugs when medically appropriate and necessary, but opposes government-mandated coverage of specific pharmaceuticals, whether for FDA-approved or off-label uses. AMCP supports having managed care organizations and third party payors consider the following criteria before deciding whether to provide coverage of FDA-approved drugs for certain off-label uses:

- Whether the drug has been proven effective and accepted for the treatment of the specific medical condition for which it has been prescribed according to the current edition of American Hospital Formulary Service Drug Information® (AHFS-DI®), Thomson Micromedex DRUGDEX®, Clinical Pharmacology, or the National Comprehensive Cancer Network (NCCN) Drug and Biologics Compendium™.
- Whether the drug is recommended for the particular condition involved, and has been proven to be safe and effective for that condition according to reproducible formal clinical studies, the results of which have been published in peer-reviewed evidence-based medical literature. Randomized controlled trials are preferred over observational research or case studies.

(See AMCP Where We Stand Position Statement – *Off-Label Use of Pharmaceuticals*)

Pharmacist's Role in Formulary Management

Policy 9922

11/01/1999 Introduced 03/01/2004 Revised 12/01/2008 Revised 10/01/2010 Reapproved AMCP supports the use of evidence-based formularies that enhance quality of pharmaceutical care while lowering medication costs. AMCP recognizes that formulary management is an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together in an effort to produce the best clinical, humanistic, and economic outcomes. AMCP further recognizes that pharmacists are key to the success of formulary management. Pharmacists determine the P&T Committee agenda; analyze and disseminate scientific, clinical, and health economic information for P&T Committee member review; follow-up with research when necessary; and communicate P&T Committee decisions to health plan prescribers, other health care professionals, and patients.

(See AMCP Concepts in Managed Care Pharmacy – Formulary Management and AMCP Where We Stand Position Statement – Formularies).

Therapeutic Interchange

Policy 9928

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Revised AMCP supports the use of evidence-based therapeutic interchange programs as a part of a comprehensive approach to quality, costeffective patient care. AMCP believes that therapeutic interchange represents an efficient use of medical resources that helps keep medical costs down, improves the patient's access to more affordable health care, and enhances the patient's quality of life. The programs are designed to work in conjunction with other tools that health care professionals use to promote quality medical outcomes, add value, and increase affordability to patients and payers. Therapeutic interchange is not always about lower drug costs, however. Frequently, therapeutic interchange occurs when overall health care savings can be achieved. In some instances, replacing one drug with a more expensive drug may result in fewer treatment failures, better patient adherence to the treatment plan, fewer side effects, and improved clinical outcomes.

(See AMCP Where We Stand Position Statement – *Therapeutic Interchange*)

**Best Practice Principles** 

Policy 0002

02/01/2000 Introduced

AMCP supports identifying, recognizing and exchanging best practices in managed care pharmacy in all practice sites. Furthermore AMCP supports the inclusion of best practice principles in mentoring and preceptor programs.

# 02/01/2005 Reapproved 11/01/2009 Revised

Development of Performance Measures

Policy 0006

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Revised 02/21/2018 Revised AMCP recommends the continued development of performance measures, and partners with complementary organizations to ensure alignment of all health care stakeholders in the pursuit of improvements in the quality of patient care management.

Patient Adherence and Persistence

Policy 0115

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Revised

**Utilization Management** 

Policy 0401

02/01/2004 Introduced 12/01/2008 Reapproved 10/01/2012 Revised 02/08/2017 Revised AMCP supports programs that encourage patients to adhere to prescribed treatment regimens and continue those regimens (persistence) for maximum therapeutic benefit. Programs should be developed with knowledge of the patient's history, value for the prescribed treatment, and expected positive therapeutic outcome. AMCP believes that the pharmacist, as the medication management professional, has an important role in this process. Such programs should use comprehensive communications and evidence-based approaches to support patient adherence and persistence.

AMCP supports the role of utilization management in the provision of quality, cost-effective prescription drug benefits. The fundamental goal of utilization management is to promote the appropriate and cost-effective use of medications. Pharmacists in all practice settings must work collaboratively to develop specific policies and procedures to ensure that the utilization management process is administered in the most efficient manner possible, is fully compliant with statutory and regulatory requirements and provides members, pharmacists and prescribers with an evidence-based, rational process to promote appropriate drug use. Examples of utilization management strategies used within a prescription drug benefit include prior authorization, step therapy, quantity management, drug utilization review (DUR), site of service steerage, and the formulary exception process.

(See AMCP Concepts in Managed Care Pharmacy – Prior Authorization).

Comparative Effectiveness of Prescription Drugs

Policy 0501

02/05/2005 Introduced 11/01/2009 Reapproved 02/01/2014 Revised The purpose of comparative effectiveness research is to assist consumers, clinicians, purchasers and policymakers to make informed decisions that will improve health care at both the individual and population levels. The Academy supports research and the development of practical tools to provide guidance on the comparative effectiveness and value of prescription drugs to improve patient outcomes. Recent legislation, including the Affordable Care Act, has directed new funding toward this research. The Academy believes that the federal government must continue to assume principal responsibility for sponsoring this type of research. Such research is a fundamentally necessary component of any rational approach to determining the value and usefulness of prescription drugs. Currently, only limited authoritative research exists that distinguishes the effectiveness and safety profile offered by any particular drug as compared to other drugs in the same or a similar treatment class. The Academy believes that patient treatment decisions must take into account the clinical effectiveness and safety of prescription drugs and that a decision to utilize prescription drugs must be based upon the strength of credible scientific evidence and best practices.

(See AMCP Where We Stand Position Statement – *Comparative Effectiveness of Prescription Drugs*)

Pharmacy & Therapeutics (P&T) Committees-Advisory Role

Policy 0602

02/01/2006 Introduced 12/01/2010 Reapproved Drug Utilization Management

Policy 0905

06/01/2009 Introduced 12/01/2013 Revised

Decision-making in the Absence of Evidence-based Data

Policy 1004

10/01/2010 Introduced 04/07/2015 Reapproved

AMCP recognizes that the clinical staff of a prescription benefit management (PBM) company or health plan is professionally responsible for the formulary and clinical decisions of the plan. Therefore, AMCP believes each organization that uses a pharmacy and therapeutics (P&T) committee should designate whether the committee's decisions are advisory or binding.

AMCP supports drug utilization management tools and formal prospective, concurrent or retrospective programs which utilize the principals of evidence based medicine to consider clinical appropriateness, cost effectiveness, patient safety and patient outcomes. Drug utilization management works ideally when coupled with a quality assurance strategy. Applications of drug utilization management may include, but are not limited to, refining practice guidelines, supporting medication therapy management, developing prior authorization and dose optimization criteria, benefit design, and channel management strategies.

AMCP recommends that managed care organizations exhibit due diligence in information gathering and document the rationale for decisions related to coverage in the absence of evidence-based data.

Maximum Allowable Cost (MAC) Pricing

Policy 1301

10/01/2013 Introduced

AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care Legislation that allows the government to dictate benefits. reimbursement terms of a private contract between a payer and a pharmacy or that mandates that the payer disclose proprietary pricing methodology is not an appropriate focus of government regulation. Further, AMCP believes that competitive negotiations between parties are more likely to provide fair and equitable reimbursement on drugs dispensed. AMCP does not support the intervention of government into private contracts to require payers to advise pharmacies on where to purchase their drugs; that is an unnecessary and inappropriate intrusion into the private arrangements of a pharmacy with its supplier. This type of government mandate takes away the incentive for a pharmacy to make wise purchasing decisions. The payers and consumers will not benefit from a system of government mandated payments to a private entity; rather it will decrease competition and further drive up the cost of the prescription drug benefit.

(See AMCP Where We Stand Position Statement – Government Regulation of Prescription Drug Prices)

Formularies Offered by Part D Insurance Plans Provide Patients with Access to Effective, Safe and Affordable Medications

Policy 0704

09/01/2007

AMCP Opposes a Government-Mandated National Formulary. The Academy of Managed Care Pharmacy (AMCP) supports the current law that requires Medicare Part D drug benefit plans to develop and manage their own drug formularies. The Academy opposes proposals that would give the federal government responsibility for establishing a single "national formulary" that these plans would be required to offer to their Part D beneficiaries.

(See AMCP Medicare Part D Concept Series – Formularies Offered by Part D Insurance Plans Provide Patients with Access to Effective, Safe and Affordable Medications)

Co-payment Offset Programs

Policy 1302

02/01/2013 Introduced

AMCP is supportive of programs that help patients afford their prescription drugs. However, some programs can needlessly encourage the use of more expensive brand-name products over their generic counterparts. They can also undermine the formulary development process by encouraging the use of products that have lower cost therapeutic alternatives. Patient safety can also be threatened when prescriptions are frequently transferred between

retail pharmacies. Therefore, AMCP is opposed to manufacturer coupon programs that are promotional in nature and are not means-tested.

(See AMCP Where We Stand Position Statement – *Co-Payment Offset Program*)

Coverage of Drugs under Part B versus Part D

Policy 1303

02/01/2013 Introduced

The administrative burdens resulting from certain medications being eligible for coverage either under Part B or Part D has created confusion, delay and expense for all involved: beneficiaries, Part D plans, providers and the Medicare program itself. The Academy of Managed Care Pharmacy suggests that remedial legislative action on this issue is one of the most important corrective actions that Congress can take as it addresses modifications to the current Medicare Part D program. It is also an issue that can have a dramatic, valuable impact on beneficiary health and well-being, as well as taxpayer savings.

### AMCP Recommends:

- 1. The Academy recommends that the following drugs, which can be self-administered, be moved from Part B, where they are covered in certain situations, to Part D coverage in all situations:
  - Oral chemotherapeutics
  - · Oral anti-emetics
  - Inhalation and blood glucose monitoring DME supply drugs
  - Immunosuppressants
- 2. To decrease confusion, all vaccines should be covered under the same part of the Medicare benefit—in this case Part B.
- 3. The Academy recommends that Medicare Part D plans that have made a coverage determination that can be demonstrated to have been in good faith, and after exercising due diligence, be exempt from legal jeopardy.

(See AMCP Medicare Part D Concept Series – Coverage of Drugs under Part B versus Part D)

Direct-to-Consumer Advertising of Prescription Products

Policy 9906

11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP supports direct-to-consumer advertising that educates the public about disease symptoms and available treatment options. AMCP discourages the use of direct-to-consumer advertising that promotes specific prescription drug products.

(See AMCP Where We Stand Position Statement – *Direct-to-Consumer Advertising of Prescription Products*).

Regulation of the Prescription Drug Benefit

Policy 1402

10/07/2014 Introduced

The Academy opposes statutory and regulatory proposals that unduly restrict the ability of pharmacists working within managed care organizations, including pharmacy benefit managers, from using tools and services that are essential for the management of a prescription drug benefit. These types of proposals are objectionable if they go beyond procedural protections and enter an arena traditionally within the purview, expertise and experience of health care professionals.

(See AMCP Where We Stand Position Statement – Regulation of the Prescription Drug Benefit)

Value Based Contracts

Policy 1801

04/23/2018 Introduced

AMCP supports the development of value-based contracts (VBCs) as an innovative means of shifting health care payment models from focusing on volume to focusing on value. The shift in payment models is expanding beyond the delivery of health care services to encompass models of compensation between payers and biopharmaceutical manufacturers. VBCs have emerged as a mechanism that payers may use to better align their contracting structures with broader changes in the overall health care system. A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures. AMCP is committed to advocating for legislative and regulatory changes when necessary to address barriers to the optimal execution of VBCs.

Pharmaceutical Information Exchange

Policy 1804

02/21/2018

AMCP supports ongoing bi-directional exchange of information between payors and pharmaceutical manufacturers in advance of FDA approval of products to ensure effective planning, budgeting, and forecasting for benefit development.

## **FRAUD WASTE AND ABUSE**

Needle Exchange Programs	AMCP supports the use of needle exchange programs for substance abusers to reduce the risk of transmission of the human
Policy 9915	immunodeficiency virus (HIV), hepatitis B and C viruses, and other communicable diseases in intravenous drug users.
11/01/1999 Introduced	
03/01/2004 Reapproved	
12/01/2008 Reapproved	
10/01/2012 Reapproved	
02/08/2017 Reapproved	
Substance Abuse Programs	AMCP supports the involvement of pharmacists in the development and promotion of programs that prevent substance abuse and
Policy 0008	educate about substance use disorder. AMCP recommends pharmacists monitor drug use to identify cases of misuse or abuse
02/01/2000 Introduced	and work with providers and patients on the best evidence-based,
02/01/2005 Reapproved	therapeutic intervention and monitoring plan.
11/01/2009 Reapproved 02/21/2018 Revised	
02/21/2018 Neviseu	
Evidence-based Advertising of	AMCP supports federal regulatory requirements that ensure that
Pharmaceuticals	prescription and non-prescription advertising to health care practitioners and patients contains claims that are supported by
Policy 0012	evidence-based research, and that such advertising does no contribute to drug abuse or indiscriminate use of medication.
02/01/2000 Introduced	
02/01/2005 Revised	
11/01/2009 Revised	
12/01/2013 Revised	
Pharmacist Recovery Programs	AMCP supports the establishment by state boards of pharmacy of
Policy 0021	counseling, treatment, prevention, and rehabilitation programs for pharmacists, pharmacy technicians and student pharmacists who
Folicy 0021	are subject to physical or mental impairment due to the influence
02/01/2000 Introduced	of drugs — including alcohol — or other causes, when such
02/01/2003 Revised	impairment has potential to adversely impact their abilities to
02/01/2008 Revised	function properly in a professional capacity. AMCP supports the
10/01/2012 Reapproved	empowerment of state boards of pharmacy to use discretionary
, , , , , , , , , , , , , , , , , , , ,	powers in determining employment waiver requests relating to the
	licensure of impaired pharmacists and pharmacy technicians.

**Pharmaceutical Counterfeiting** 

Policy 0505

10/01/2005 Introduced 02/01/2010 Reapproved

AMCP supports efforts to increase health care professional and public awareness of medication counterfeiting. AMCP supports the purchase and handling of medications in ways that enhance the transparency and integrity of the drug product supply chain and encourages pharmacists to identify instances of drug product counterfeiting. AMCP encourages efforts to provide consumers and health care professionals with information on how to avoid counterfeit drug products and how to recognize, respond to, and report encounters with suspicious drug products. AMCP backs efforts to foster research and education on the extent, methods, and impact of drug product counterfeiting and on strategies for preventing and responding to drug product counterfeiting.

Drug Abuse/Illicit Drug Use

Policy 0604

04/01/2006 Introduced 12/01/2010 Reapproved 04/07/2015 Reapproved AMCP supports legislation that balances the need for patient access to medications (e.g. pseudoephedrine and narcotics) for legitimate medical purposes with the need to prevent diversion and illicit use.

Fraud, Waste and Abuse in the Medicare Part D Prescription Drug Benefit

Policy 1002

06/01/2010 Introduced

AMCP is deeply concerned about reports of fraud, waste and abuse within the Medicare Part D prescription drug benefit. Fraud, waste and abuse are unacceptable within any health care program, especially within health care programs that are financed through taxpayer dollars. AMCP recognizes the seriousness of this problem and is supportive of efforts that would reduce the instance of fraudulent activity, such as lifting the current "any willing provider" requirement and amending current law to allow plans to withhold payments to pharmacies that are suspected of fraud.

(See AMCP Where We Stand Position Statement – Fraud, Waste and Abuse in the Medicare Part D Prescription Drug Benefit)

**Audits of Pharmacy Providers** 

Policy 1103

12/01/2011 Introduced 10/01/2012 Reapproved Audits serve two main purposes: 1) detecting fraud, waste and abuse, and 2) validating data entry and documentation to ensure they meet regulatory and contractual requirements. The audit process should be transparent and have a fair design and implementation. The managed care organization should supply the pharmacy provider with a document that defines the requirements on which it may base an audit. The actual audits should be conducted in a manner that leads to continuous quality improvement of the services of the provider, rather than as a source of revenue. Further, the provider must review and be comfortable with these documents before it agrees to a contract. It is imperative that pharmacists-in-charge, and their staff, understand the dispensing and billing requirements and the implications of noncompliance. A bilateral professional level of performance can make

the audit process run smoothly, be educational and improve quality.

(See AMCP Model Audit Guidelines for Pharmacy Claims)

Fraud, Waste and Abuse in Prescription Drug Benefit

Policy 1105

10/01/2011 Introduced

- Fraud
  - AMCP supports efforts by both federal and state governments that enhance law enforcement's ability to combat the actions of individuals who falsify prescription information or providers who write prescriptions for patients who intend to abuse the drugs.
  - AMCP supports efforts to encourage the adoption of electronic prescribing systems, which could reduce the incidence of fraud at the pharmacy point-of-sale.
  - AMCP is opposed to requirements that managed care organizations contract with any pharmacy willing to meet the terms and conditions of an organization's contract, also known as "any willing provider" requirements. Without such requirements, a managed care organization may refuse to contract with a pharmacy that is suspected of fraudulent activity, such as a pharmacy that files claims and receives payments for prescriptions that are never filled.

### Waste

- AMCP supports exemptions from these laws that would allow a health plan or PBM to suspend payment when there is credible evidence of fraud.
- AMCP supports efforts to make generic substitution an easy process for pharmacists and prescribers.
- AMCP opposes regulations that would unnecessarily place a burden on either party in order to make a substitution.
- AMCP supports allowing managed care organizations the flexibility to design pharmacy benefits that encourage the use of therapeutic treatment options that are most appropriate in terms of both patient outcomes and costs to both the patient and payer.

### Abuse

- AMCP supports measures to prevent abuse of prescription drugs as well as prescription drug benefit plans.
- AMCP supports programs that gather dispensing information about controlled substances so that the pharmacist has a resource for checking "pharmacy and doctor shopping" patterns.
- AMCP supports sensible changes to current law that would allow Part D plan sponsors to help combat the problem of prescription drug abuse.

(See AMCP Where We Stand Position Statement – Fraud, Waste and Abuse in Prescription Drug Benefits)

Management of Opioids

Policy 1306

06/01/2013 Introduced 04/23/2018 Revised

The Academy of Managed Care Pharmacy (AMCP) is focused on identifying the improper use of opioids and the enormous costs to Society that go beyond traditional health care costs. AMCP wants to assure the proper management of patients suffering from uncontrolled pain, cancer and those who are terminally ill, while limiting the abuse and diversion of opioids. Policies that address the opioid epidemic must strike a balance that maintains appropriate access for those patients.

AMCP advocates for sensible changes to existing laws at the federal and state level to authorize implementation of patient safety programs such as requiring electronic prescribing (e-prescribing) of opioids, updating Risk Evaluation and Mitigation Strategy (REMS) and continuing medication education for prescribers. AMCP also supports the ongoing development and implementation of prescription drug monitoring programs (PDMPs) and expanding access to PDMPs to include health plans and pharmacy benefit managers (PBMs). Giving those organization access to PDMPs will enhance their ability to recognize and assist patients that may be abusing opioids while identifying those patients that may be a source of diversion.

AMCP encourages strategies addressing overdose education including naloxone distribution programs as well as the proper disposal of unused prescription opioids and Drug Takeback Days as tools to combat diversion in communities across the country. AMCP supports a legislative and regulatory framework that increases the ability of health plans and PBMs to effectively manage the use of opioids, in a clinically appropriate manner and limit the potential for abuse, using managed care strategies in collaboration with others in the health care community.

006/01/2013 Introduced\*

04/23/2018 Revised (\*subject originally included policy on abuse deterrent and tamper resistant formulations, those subjects now included in Policy 1802)

National Provider Number

Policy 0015

02/01/2000 Introduced 02/01/2005 Revised 02/01/2010 Reapproved AMCP supports the use of the federally issued National Provider Identifier, a unique universal identifier number for each healthcare provider.

Therapeutic Purpose Inclusion AMCP encourages the inclusion of the therapeutic purpose on all on Prescriptions and Medication prescriptions and medication orders. Orders Policy 0027 11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Revised 03/27/2017 Reapproved Disposal of Needles and AMCP supports the development and implementation of safe systems and procedures for the disposal of used needles and **Syringes** syringes by patients outside of health care facilities. Policy 0113 11/01/2001 Introduced 11/01/2005 Reapproved 11/01/2009 Reapproved 02/21/2018 Reapproved Redispensing of Unused AMCP supports programs for the return, reuse and payment credit Medications of unused medications from state programs, long-term care facilities, and other medical facilities. Policy 0703 Authority to redispense medication should only be permitted 06/01/2007 Introduced when: Unused medication has not left the supervision of a health care professional or designated representative • Unused medication is in the original sealed packaging (e.g. unit of use packaging) • Unused medication has been properly stored Unused medication has not expired In addition, such programs should: • Provide an equal standard of care for all patients • Decrease waste • Decrease medication costs for both patient and benefit providers • Minimize environmental impact of discarded medication • Ensure the integrity and safety of the product Protect the privacy of the original recipient Comply with state and federal requirements

Abuse Deterrent and Tamper Resistant Formulations

Policy 1802

04/23/2018 Introduced

AMCP encourages the U.S. Food and Drug Administration (FDA) to use its expertise to establish standards for the definition of "abuse-deterrent" and "tamper resistant." The Agency should also require that manufacturers of those products undertake reasonable post-marketing surveillance studies that will help assess the impact of the products on both the abuse of the specific product, as well as overall rates of abuse. Because opioids may vary in their clinical effectiveness and abuse potential, AMCP supports expanding the ability of health plans to clinically manage these products. Therefore, AMCP does not support mandating the use of "abuse deterrent" and "tamper resistant products." AMCP maintains that such products are not clinically necessary for all patients.

## **GENERICS**

**Generic Drug Products** 

Policy 9911

11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Revised 02/01/2014 Revised AMCP encourages pharmacists and managed health care systems to promote the use and benefits of FDA-approved and therapeutically equivalent generic drug products as safe, effective, and costeffective alternatives to brand-name equivalents. AMCP supports legislative and regulatory changes that would promote the development and use of safe, efficacious and equivalent generic drugs and eliminate barriers that can unnecessarily delay the entry of the generic drugs into the marketplace. AMCP believes that Congress must ensure that the FDA has access to adequate resources in order to review and process applications for generic drugs and eliminate unnecessary delays of their approval. AMCP opposes state and federal legislative and regulatory provisions that would restrict the right of pharmacists, in collaboration with prescribers and patients, to exercise their professional judgment in choosing the most appropriate generic or brand-name equivalent products for patients.

(See AMCP Where We Stand Position Statement – *Generic Drugs*) (See AMCP Where We Stand Position Statement – *Biosimilar Drug Therapies*)

Interchange of Narrow Therapeutic Index (NTI) Drugs

Policy 9912

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved AMCP supports the Food and Drug Administration's (FDA) position that when an FDA-approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be assured that they will see the same clinical results and safety profile as with the equivalent brand name product. Therefore, NTI drugs should not be considered as a separate category for purposes of generic substitution. AMCP believes that pharmacists, in consultation with prescribers, should have the right to use their professional judgment and knowledge of the available scientific information in determining when to substitute a generic product.

(See AMCP Where We Stand Position Statement – *Interchange of Narrow Therapeutic Index (NTI) Drugs*).

Generic Drug User Fee Program

Policy 1101

02/01/2011 Introduced

AMCP supports an effective generic drug user fee program to provide more resources that will reduce delays in the generic drug review process due to lack of appropriate Food and Drug Administration funding. AMCP believes that a generic drug user fee program must ensure that the resources invested produce a meaningful program with measureable results. Generic drug user fees should be adequate to generate resources assigned to the Office of Generic Drugs, but such fees should not hinder the benefit to society provided by cost-effective medications.

## **HEALTH INFORMATION/ AUTOMATION TECHNOLOGY**

**Drug and Device Recalls** 

Policy 0009

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP supports the use of technologies to enhance communication of recall information to all relevant parties including patients who may have received such products.

Electronic Pharmacy Data Processes

Policy 0011

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP supports the use of national standards for: the electronic transfer of patient medical data, particularly electronic pharmacy claims submissions; the electronic transmission of prescription information; the integrity and accuracy of information systems; the electronic and practical processes for drug use evaluation; and the maintenance of the privacy of electronically transferred patient identifiable health information.

Pharmacist Access to Patient Information

Policy 0017

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP supports the right of pharmacists in all practice environments to have access to patient identifiable medical and pharmacy information necessary for use in treatment, payment and health care operations to achieve optimal therapeutic outcomes.

**Pharmacy CPT Codes** 

Policy 0022

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/01/2014 Reapproved AMCP supports the use and expansion of pharmacy-specific codes listed in the American Medical Association's Physicians' Current Procedural Terminology (CPT) coding structure to assist pharmacists in coding for their professional services.

**Health Information Technology** AMCP encourages the use of and implementation of evolving health in Pharmacy Practice information technologies in all aspects of pharmacy (dispensing, counseling, etc.) as an adjunct to a pharmacist's professional Policy 0102 oversight to increase quality and efficiency and extend limited professional resources. The Academy also encourages the inclusion 03/01/2001 Introduced of instruction concerning these tools and their applications in the 02/01/2006 Revised curricula of schools of pharmacy and their acceptance and 12/01/2010 Revised recognition by state and federal governments. Electronic Exchange of e-AMCP supports the electronic transmission of prescriptions **Prescribing Information** between the prescriber to the pharmacist as the preferred method of prescribing, and supports allowing managed health care systems to have access to that electronic transmission for appropriate Policy 0114 purposes. AMCP supports federal and state legislative and 11/01/2001 Introduced regulatory provisions that provide for the electronic transmission of 02/01/2005 Revised prescription information between prescriber and pharmacist. The 11/01/2009 Revised Academy believes that the electronic exchange of prescription, drug 04/23/2018 Revised benefit, and drug information improves patient drug therapy, enhances the collection and analysis of patient data, increases operational efficiencies and optimizes health care outcomes. National Health Information AMCP supports the development and adoption of a national health Network information network and recommends that this network include a patient's prescription drug record. This network will be Policy 0504 instrumental in improving patient outcomes and quality of care. 10/01/2005 Introduced 11/01/2009 Reapproved **Technology in Prescription Drug** AMCP supports the development, advancement and use of **Delivery Systems** technology as a means of improving efficiency, quality and affordability in the delivery of prescription drugs to patients. Policy 0603 Electronic prescribing, automated systems for claims processing, drug counting, labeling, filling and delivery of prescription orders 02/01/2006 Introduced and information systems that track and chart prescription drug use 02/01/2008 Reapproved and analyze integrated health data are valuable tools that are 10/01/2012 Reapproved improving the practice of pharmacy. Encouraging the use of these tools and future development of new innovative technologies and information systems may advance productivity, improve customer satisfaction, enhance accuracy and reduce errors in the delivery of prescription drugs. (See AMCP Where We Stand Position Statement – *Use of* Technology in the Prescription Drug Delivery System) **Electronic Health Information** AMCP supports the implementation and expanded use of Technology electronic health information technology, including electronic health records and electronic prescribing, provided that there are Policy 0704 appropriate mechanisms in place to protect the privacy of patients. Electronic health information technology promises 02/01/2008 Introduced improvement in quality and efficiency, data collection and 10/01/2012 Reapproved reporting and may help restrain cost increases. Use of this

technology will require national standards ensuring patient privacy

and system interoperability that are developed in concert with the federal government and patient, provider and payer groups. (See AMCP Where We Stand Position Statement - *Electronic Health Information Technology*)

Electronic Communication of Prescription Information

Policy 1001

06/01/2010 Introduced

AMCP supports the utilization of electronic prescription information, provided that there are reasonable and reliable assurances of authenticity, accountability, accuracy and confidentiality. AMCP believes that optimum use of electronic prescription information can be achieved through the adoption of national standards that promote the interoperability. Such standards, statutory or private, must be designed to supports the efficient, practical provision of health care treatment and business operations.

(See AMCP Where We Stand Position Statement – *Electronic Communication of Prescription Information*)

Use of Technology

Policy 1307

02/01/2013 Introduced

The Academy of Managed Care Pharmacy (AMCP) supports the implementation and expanded use of health information technology (HIT), including electronic health records and electronic prescribing. AMCP also supports the use of technology in the dispensing and delivery of prescription drugs to patients. AMCP supports the adoption and use of national standards that promote system interoperability among providers and *payers* and the use of requisite sets of functional elements necessary for optimizing medication access, safety and cost-effective utilization.

(See AMCP Where We Stand Position Statement – *Use of Technology in the Health Care System*)

## **HEALTH INSURANCE MARKETPLACES**

Any Willing Provider Legislation

Policy 9901

11/01/1999 Introduced 03/01/2004 Reapproved 02/01/2005 Revised 01/01/2009 Reapproved 07/29/2014 Revised AMCP supports the ability of managed care organizations to selectively contract with only those providers necessary to enable the organization to provide patients with adequate access to pharmacy services and quality, cost-effective health care. By selectively contracting with providers, managed care organizations assure that patients can receive the best care, have access to the providers they need and reduce the likelihood that valuable health care resources will be wasted through inappropriate use. Therefore, the Academy opposes legislation that would require managed care organizations to contract with any provider meets the terms and conditions of the organization, whether or not it can be shown that the provider meets the geographic access needs and/or quality standards of the health plan.

(See AMCP Where We Stand Position Statement - Any Willing Provider Legislation, October 2010).

Government-Mandated Pharmacy Benefits

Policy 0101

03/01/2001 Introduced 06/01/2006 Revised

**Prescription Drug Coverage** 

Policy 9925

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Revised AMCP supports the right of managed care organizations and their clients to independently make decisions with regard to health benefits that meet the medical needs of specific patient populations while being compassionate, medically sound, timely, and fiscally responsible. Federal and state legislation and regulations should not hinder a health care delivery system's ability to provide customized benefits that assure value and quality patient care for specific patient populations, yet remain affordable.

(See AMCP Where We Stand Position Statement – Government-Mandated Pharmacy Benefits)

AMCP supports the inclusion of prescription drug coverage in all health care benefit programs, including those administered by the government (e.g. Medicare, Medicaid, health insurance exchanges). Access to a comprehensive prescription drug benefit coupled with proper use of those medications, has been shown to reduce the severity of, and complications arising from many common illnesses. Failure to provide prescription drug coverage means fewer Americans will have effective drug programs available, thereby diminishing their access to medication therapy and increasing the chance that they will require more intensive, costly health care services such as surgery and/or hospitalization. AMCP also supports granting flexibility to managed care organizations to develop clinically sound, evidence-based benefits free from arduous mandates.

(See AMCP Where We Stand Position Statement – *Prescription Drug Coverage*).

Co-payment Offset Programs

Policy 1302

02/01/2013 Introduced

AMCP is supportive of programs that help patients afford their prescription drugs. However, some programs can needlessly encourage the use of more expensive brand-name products over their generic counterparts. They can also undermine the formulary development process by encouraging the use of products that have lower cost therapeutic alternatives. Patient safety can also be threatened when prescriptions are frequently transferred between retail pharmacies. Therefore, AMCP is opposed to manufacturer coupon programs that are promotional in nature and are not means-tested.

(See AMCP Where We Stand Position Statement – *Co-Payment Offset Program*)

Government Negotiation of Prescription Drug Prices

Policy 1304

02/01/2013 Introduced

The Academy of Managed Care Pharmacy (AMCP) opposes legislation that would allow or require the federal government to negotiate prescription drug prices on behalf of Medicare Part D plan sponsors. The Academy supports the current structure of the Part D benefit that relies on the concept that drug price concessions are best achieved by negotiations by participating drug plan sponsors who themselves are motivated by the competitive need to provide the most cost-effective and clinically appropriate drug benefits possible. AMCP believes proposals to repeal the noninterference provision would introduce consequences that must be thoughtfully considered before action is taken.

(See AMCP Medicare Part D Concept Series – Government Negotiation of Prescription Drug Prices)

Competitive Marketplace

Policy 0901

02/01/2009 Introduced

AMCP believes that a health care delivery system that is based upon an open and competitive marketplace will provide greater value to patients and payers than a system that is one-size-fits-all and relies on centralized governmental controls and regulatory mandates. Through innovative and integrated strategies that focus on patient education, quality assurance and drug utilization management, managed care pharmacy has been able to deliver a pharmacy benefit that is clinically sound, accessible and affordable. The most appropriate role of the government in the prescription drug marketplace is as a regulator of the market and protector of consumer's interest and, in the case of public programs, as a financing entity. AMCP will continue to work closely with government officials, agencies and other payers to constantly refine the services and products sought through pharmacy benefits.

(See AMCP Where We Stand Position Statement – *Competitive Marketplace*)

Regulation of the Prescription Drug Benefit

Policy 1402

10/07/2014 Introduced

The Academy opposes statutory and regulatory proposals that unduly restrict the ability of pharmacists working within managed care organizations, including pharmacy benefit managers, from using tools and services that are essential for the management of a prescription drug benefit. These types of proposals are objectionable if they go beyond procedural protections and enter an arena traditionally within the purview, expertise and experience of health care professionals.

(See AMCP Where We Stand Position Statement – *Regulation of the Prescription Drug Benefit*)

## **MANAGED CARE PHARMACY TOOLS**

**Drug Use Evaluation** 

Policy 9909

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Reapproved 02/08/2017 Reapproved AMCP recognizes the value of drug use evaluation (DUE) as a means of improving the quality of patient care, enhancing therapeutic outcomes, and reducing inappropriate pharmaceutical expenditures, thus reducing overall health care costs. Using DUE information, managed care pharmacists can identify prescribing trends in patient populations and initiate corrective action to improve drug therapy for groups of patients, as well as individuals.

(See AMCP Concepts in Managed Care Pharmacy – *Drug Use Evaluation*)

### **Formularies**

Policy 9910

11/01/1999 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 02/08/2017 Revised 04/23/2018 Revised AMCP supports the use of appropriately designed formularies as quality-enhancing, cost-effective pharmaceutical care tools that assist members of the health care team in effectively managing a patient's total medical care regimen. A formulary enhances quality of care by encouraging the use of those prescription medications that are demonstrated to be safe, cost effective, with the highest probability of leading to positive patient outcome. To this end, formulary decisions are based primarily on sound clinical evidence. Cost considerations should influence decisions only after safety, efficacy and therapeutic need have been assessed. A formulary works best when it supports and operates in conjunction with other tools that promote quality and optimal results, such as drug utilization review and medical treatment guidelines. In addition, the value of a formulary is maximized when it is part of an integrated patient care continuum, which encourages physicians, pharmacists, and other care givers to work together to ensure positive outcomes and cost effective results.

(See AMCP Where We Stand Position Statement - Formularies, and AMCP Concepts in Managed Care Pharmacy - Formulary Management)

Off-Label Use of Pharmaceuticals

Policy 9916

11/01/1999 Introduced 02/01/2003 Revised 02/01/2008 Reapproved 10/01/2012 Reapproved The Academy of Managed Care Pharmacy supports off-label use of FDA-approved drugs when medically appropriate and necessary, but opposes government-mandated coverage of specific pharmaceuticals, whether for FDA-approved or off-label uses. AMCP supports having managed care organizations and third party payors consider the following criteria before deciding whether to provide coverage of FDA-approved drugs for certain off-label uses:

- Whether the drug has been proven effective and accepted for the treatment of the specific medical condition for which it has been prescribed according to the current edition of American Hospital Formulary Service Drug Information® (AHFS-DI®), Thomson Micromedex DRUGDEX®, Clinical Pharmacology, or the National Comprehensive Cancer Network (NCCN) Drug and Biologics Compendium™.
- Whether the drug is recommended for the particular condition involved, and has been proven to be safe and effective for that condition according to reproducible formal clinical studies, the results of which have been published in peer-reviewed evidence-based medical literature. Randomized controlled trials are preferred over observational research or case studies.

(See AMCP Where We Stand Position Statement - Off-Label Use of Pharmaceuticals)

Pharmacist's Role in Formulary Management

Policy 9922

11/01/1999 Introduced 03/01/2004 Revised 12/01/2008 Revised 10/01/2010 Reapproved AMCP supports the use of evidence-based formularies that enhance quality of pharmaceutical care while lowering medication costs. AMCP recognizes that formulary management is an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together in an effort to produce the best clinical, humanistic, and economic outcomes. AMCP further recognizes that pharmacists are key to the success of formulary management. Pharmacists determine the P&T Committee agenda; analyze and disseminate scientific, clinical, and health economic information for P&T Committee member review; follow-up with research when necessary; and communicate P&T Committee decisions to health plan prescribers, other health care professionals, and patients.

(See AMCP Concepts in Managed Care Pharmacy - Formulary Management and AMCP Where We Stand Position Statement - Formularies)

### Therapeutic Interchange

Policy 9928

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Revised AMCP supports the use of evidence-based therapeutic interchange programs as a part of a comprehensive approach to quality, cost-effective patient care. AMCP believes that therapeutic interchange represents an efficient use of medical resources that helps keep medical costs down, improves the patient's access to more affordable health care, and enhances the patient's quality of life. The programs are designed to work in conjunction with other tools that health care professionals use to promote quality medical outcomes, add value, and increase affordability to patients and payers. Therapeutic interchange is not always about lower drug costs, however. Frequently, therapeutic interchange occurs when overall health care savings can be achieved. In some instances, replacing one drug with a more expensive drug may result in fewer treatment failures, better patient adherence to the treatment plan, fewer side effects, and improved clinical outcomes.

(See AMCP Where We Stand Position Statement - Therapeutic Interchange)

### **Best Practice Principles**

Policy 0002

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Revised AMCP supports identifying, recognizing and exchanging best practices in managed care pharmacy in all practice sites. Furthermore AMCP supports the inclusion of best practice principles in mentoring and preceptor programs.

# Development of Performance Measures

Policy 0006

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Revised 02/21/2018 Revised AMCP recommends the continued development of performance measures, and partners with complementary organizations to ensure alignment of all health care stakeholders in the pursuit of improvements in the quality of patient care management.

# Patient Adherence and Persistence

Policy 0115

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Revised AMCP supports programs that encourage patients to adhere to prescribed treatment regimens and continue those regimens (persistence) for maximum therapeutic benefit. Programs should be developed with knowledge of the patient's history, value for the prescribed treatment, and expected positive therapeutic outcome. AMCP believes that the pharmacist, as the medication management professional, has an important role in this process. Such programs should use comprehensive communications and evidence-based approaches to support patient adherence and persistence.

Utilization Management	AMCP supports the role of utilization management in the provision of quality, cost-effective prescription drug benefits. The
Policy 0401	fundamental goal of utilization management is to promote the appropriate and cost-effective use of medications. Pharmacists in
02/01/2004 Introduced	all practice settings must work collaboratively to develop specific
12/01/2008 Reapproved	policies and procedures to ensure that the utilization management
10/01/2012 Revised	process is administered in the most efficient manner possible, is
02/08/2017 Revised	fully compliant with statutory and regulatory requirements and
	provides members, pharmacists and prescribers with an evidence-
	based, rational process to promote appropriate drug use. Examples
	of utilization management strategies used within a prescription drug benefit include prior authorization, step therapy, quantity
	management, drug utilization review (DUR), site of service steerage,
	and the formulary exception process.
	(See AMCP Concepts in Managed Care Pharmacy – Prior
	Authorization).
Pharmacy & Therapeutics (P&T)	AMCP recognizes that the clinical staff of a prescription benefit
Committees-Advisory Role	management (PBM) company or health plan is professionally
Policy 0602	responsible for the formulary and clinical decisions of the plan. Therefore, AMCP believes each organization that uses a pharmacy
1 oney 0002	and therapeutics (P&T) committee should designate whether the
02/01/2006 Introduced	committee's decisions are advisory or binding.
12/01/2010 Reapproved	
Decision-making in the Absence	AMCP recommends that managed care organizations exhibit due
of Evidence-based Data	diligence in information gathering and document the rationale for
Policy 1004	decisions related to coverage in the absence of evidence-based data.
,	
10/01/2010 Introduced	
04/07/2015 Reapproved	
Mail Service Pharmacies	The Academy of Managed Care Pharmacy (AMCP) believes that
Policy 1202	managed care organizations (MCOs) must have the flexibility to use mail service delivery of prescription drugs as a component of their
1 oney 1202	prescription drug benefit. Mail service pharmacies are a valuable
12/01/2012 Introduced	tool used by MCOs to increase patient safety, offer patient
	convenience, and maintain the affordability of the prescription drug
	benefit as a whole. Additionally, MCOs should have the ability to set
	patient cost-sharing levels for prescription orders filled through mail
	service pharmacies different from the patient cost-sharing levels for
	prescription orders filled through retail pharmacies.
	(See AMCP Where We Stand Position Statement – Mail Service
	Pharmacies)
Preferred Pharmacy Networks	The Academy of Managed Care Pharmacy (AMCP) supports the
Dollar 1401	ability of health plans to offer preferred pharmacy networks for
Policy 1401	their enrollees as a way of providing additional options and cost

### 07/29/2014 Introduced

savings without any diminishment of quality or patient access. Preferred pharmacy networks represent an important tool and innovation in managed care pharmacy benefits. The Academy supports the continued use of these programs as a beneficial way to maintain quality of care, access and cost effectiveness to the pharmacy benefit.

## Regulation of the Prescription Drug Benefit

Policy 1402

10/07/2014 Introduced

The Academy opposes statutory and regulatory proposals that unduly restrict the ability of pharmacists working within managed care organizations, including pharmacy benefit managers, from using tools and services that are essential for the management of a prescription drug benefit. These types of proposals are objectionable if they go beyond procedural protections and enter an arena traditionally within the purview, expertise and experience of health care professionals.

(See AMCP Where We Stand Position Statement – Regulation of the Prescription Drug Benefit)

# Medicare Part D Quality Measures

Policy 1403

10/07/2014 Introduced

The Academy recognizes the essential role of pharmacists and plans in improving the quality of care provided to patients and supports a measure development process which allows for timely integration of evidence-based medicine and feedback from stakeholders. AMCP additionally emphasizes the need to align measures across programs to promote consistency, economic efficiency, and quality across the health care system.

(See AMCP Future of Medicare Part D Statement – *Medicare Part D Quality Measures*)

#### Value Based Contracts

Policy 1801

04/23/2018 Introduced

AMCP supports the development of value-based contracts (VBCs) as an innovative means of shifting health care payment models from focusing on volume to focusing on value. The shift in payment models is expanding beyond the delivery of health care services to encompass models of compensation between payers and biopharmaceutical manufacturers. VBCs have emerged as a mechanism that payers may use to better align their contracting structures with broader changes in the overall health care system. A value-based contract is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures. AMCP is committed to advocating for legislative and regulatory changes when necessary to address barriers to the optimal execution of VBCs.

## **MEDICAID**

**Prescription Drug Coverage** 

Policy 9925

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Revised AMCP supports the inclusion of prescription drug coverage in all health care benefit programs, including those administered by the government (e.g. Medicare, Medicaid, health insurance exchanges). Access to a comprehensive prescription drug benefit coupled with proper use of those medications, has been shown to reduce the severity of, and complications arising from many common illnesses. Failure to provide prescription drug coverage means fewer Americans will have effective drug programs available, thereby diminishing their access to medication therapy and increasing the chance that they will require more intensive, costly health care services such as surgery and/or hospitalization. AMCP also supports granting flexibility to managed care organizations to develop clinically sound, evidence-based benefits free from arduous mandates.

(See AMCP Where We Stand Position Statement – *Prescription Drug Coverage*)

Government-Mandated Pharmacy Benefits

Policy 0101

03/01/2001 Introduced 06/01/2006 Revised

**Patient Satisfaction** 

Policy 0116

11/01/2001 Introduced
02/01/2006 Revised
12/01/2010 Revised
04/07/2015 Reapproved
Best Price Requirements of the
Medicaid Drug Rebate Program

Policy 0904

06/01/2009 Introduced

AMCP supports the right of managed care organizations and their clients to independently make decisions with regard to health benefits that meet the medical needs of specific patient populations while being compassionate, medically sound, timely, and fiscally responsible. Federal and state legislation and regulations should not hinder a health care delivery system's ability to provide customized benefits that assure value and quality patient care for specific patient populations, yet remain affordable.

(See AMCP Where We Stand Position Statement – Government-Mandated Pharmacy Benefits)

AMCP supports the development of mechanisms that measure the level of satisfaction patients have with pharmacy services. Acquired data may be used for quality improvement efforts, to increase public recognition of pharmacy services, monitor trends, benchmark improvement efforts, and establish the value of the array of pharmacy services to all stakeholders.

AMCP believes that the best price provisions of the Medicaid prescription drug rebate program, established by the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508), represents interference by the government into the competitive marketplace that has raised costs unnecessarily by preventing the commercial market from allowing true market dynamics to emerge. This pernicious market effect has been well documented by the U.S. Government Accountability Office (GAO), the Congressional Budget Office (CBO) and academic economists. AMCP strongly encourages

a careful re-examination of the best price program.

(See AMCP Where We Stand Position Statement – Best Price Requirements of the Medicaid Drug Rebate Program)

Government Regulation of Prescription Drug Prices

Policy 1003

06/01/2010 Introduced

AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care benefits. Government-regulated prices could greatly impair the ability of managed care organizations (MCOs) to design a competitive benefit offering that integrates clinically sound, evidence-based medication choices with delivery systems and copayment alternatives that provide beneficiaries with substantive choice. Legislation that would allow the government to regulate prescription drug prices, though well intentioned, could actually result in increased costs for many consumers in the short term and for all in the long term.

(See AMCP Where We Stand Position Statement – Government Regulation of Prescription Drug Prices)

## **MEDICARE PART D**

Any Willing Provider Legislation

Policy 9901

11/01/1999 Introduced 03/01/2004 Reapproved 02/01/2005 Revised 01/01/2009 Reapproved AMCP supports the ability of managed care organizations to selectively contract with only those providers necessary to enable the organization to provide patients with adequate access to pharmacy services and quality, cost-effective health care. By selectively contracting with providers, managed care organizations assure that patients can receive the best care, have access to the providers they need and reduce the likelihood that valuable health care resources will be wasted through inappropriate use. Therefore, the Academy opposes legislation that would require managed care organizations to contract with any provider meets the terms and conditions of the organization, whether or not it can be shown that the provider meets the geographic access needs and/or quality standards of the health plan.

(See AMCP Where We Stand Position Statement – Any Willing Provider Legislation)

**Prescription Drug Coverage** 

Policy 9925

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Revised AMCP supports the inclusion of prescription drug coverage in all health care benefit programs, including those administered by the government (e.g. Medicare, Medicaid, health insurance exchanges). Access to a comprehensive prescription drug benefit coupled with proper use of those medications, has been shown to reduce the severity of, and complications arising from many common illnesses. Failure to provide prescription drug coverage means fewer Americans will have effective drug programs available, thereby diminishing their access to medication therapy and increasing the chance that they will require more intensive, costly health care services such as surgery and/or hospitalization. AMCP also supports granting flexibility to managed care organizations to develop clinically sound, evidence-based benefits free from arduous mandates.

(See AMCP Where We Stand Position Statement – *Prescription Drug Coverage*)

Development of Performance Measures

Policy 0006

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Revised 02/21/2018 Revised AMCP recommends the continued development of performance measures, and partners with complementary organizations to ensure alignment of all health care stakeholders in the pursuit of improvements in the quality of patient care management.

Government-Mandated Pharmacy Benefits

Policy 0101

03/01/2001 Introduced 06/01/2006 Revised

AMCP supports the right of managed care organizations and their clients to independently make decisions with regard to health benefits that meet the medical needs of specific patient populations while being compassionate, medically sound, timely, and fiscally responsible. Federal and state legislation and regulations should not hinder a health care delivery system's ability to provide customized benefits that assure value and quality patient care for specific patient populations, yet remain affordable.

(See AMCP Where We Stand Position Statement – Government-Mandated Pharmacy Benefits)

**Patient Satisfaction** 

Policy 0116

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/20/15 Reapproved Fraud, Waste and Abuse in the Medicare Part D Prescription Drug Benefit

Policy 1002

06/01/2010 Introduced

AMCP supports the development of mechanisms that measure the level of satisfaction patients have with pharmacy services. Acquired data may be used for quality improvement efforts, to increase public recognition of pharmacy services, monitor trends, benchmark improvement efforts, and establish the value of the array of pharmacy services to all stakeholders.

AMCP is deeply concerned about reports of fraud, waste and abuse within the Medicare Part D prescription drug benefit. Fraud, waste and abuse are unacceptable within any health care program, especially within health care programs that are financed through taxpayer dollars. AMCP recognizes the seriousness of this problem and is supportive of efforts that would reduce the instance of fraudulent activity, such as lifting the current "any willing provider" requirement and amending current law to allow plans to withhold payments to pharmacies that are suspected of fraud.

(See AMCP Where We Stand Position Statement – Fraud, Waste and Abuse in the Medicare Part D Prescription Drug Benefit)

Government Regulation of Prescription Drug Prices

Policy 1003

06/01/2010 Introduced

AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care benefits. Government-regulated prices could greatly impair the ability of managed care organizations (MCOs) to design a competitive benefit offering that integrates clinically sound, evidence-based medication choices with delivery systems and copayment alternatives that provide beneficiaries with substantive choice. Legislation that would allow the government to regulate prescription drug prices, though well intentioned, could actually result in increased costs for many consumers in the short term and for all in the long term.

(See AMCP Where We Stand Position Statement – Government Regulation of Prescription Drug Prices)

Formularies Offered by Part D Insurance Plans Provide Patients with Access to Effective, Safe and Affordable Medications

Academy of Managed Care Pharmacy (AMCP) supports the current law that requires Medicare Part D drug benefit plans to develop and manage their own drug formularies. The Academy opposes proposals that would give the federal government responsibility for establishing a single "national formulary" that these plans would be required to offer to their Part D beneficiaries.

AMCP Opposes a Government-Mandated National Formulary. The

Policy 0704

(See AMCP'S Medicare Part D Concept Series – Formularies Offered by Part D Insurance Plans Provide Patients with Access to Effective, Safe and Affordable Medications)

09/01/2007

Fraud, Waste and Abuse in Prescription Drug Benefit

Policy 1105

10/01/2011

### Fraud

- AMCP supports efforts by both federal and state governments that enhance law enforcement's ability to combat the actions of individuals who falsify prescription information or providers who write prescriptions for patients who intend to abuse the drugs.
- AMCP supports efforts to encourage the adoption of electronic prescribing systems, which could reduce the incidence of fraud at the pharmacy point-of-sale.
- AMCP is opposed to requirements that managed care organizations contract with any pharmacy willing to meet the terms and conditions of an organization's contract, also known as "any willing provider" requirements. Without such requirements, a managed care organization may refuse to contract with a pharmacy that is suspected of fraudulent activity, such as a pharmacy that files claims and receives payments for prescriptions that are never filled.

#### Waste

- AMCP supports exemptions from these laws that would allow a health plan or PBM to suspend payment when there is credible evidence of fraud.
- AMCP supports efforts to make generic substitution an easy process for pharmacists and prescribers.
- AMCP opposes regulations that would unnecessarily place a burden on either party in order to make a substitution.

 AMCP supports allowing managed care organizations the flexibility to design pharmacy benefits that encourage the use of therapeutic treatment options that are most appropriate in terms of both patient outcomes and costs to both the patient and payer.

#### Abuse

- AMCP supports measures to prevent abuse of prescription drugs as well as prescription drug benefit plans.
- AMCP supports programs that gather dispensing information about controlled substances so that the pharmacist has a resource for checking "pharmacy and doctor shopping" patterns.
- AMCP supports sensible changes to current law that would allow Part D plan sponsors to help combat the problem of prescription drug abuse.

(See AMCP Where We Stand Position Statement – Fraud, Waste and Abuse in Prescription Drug Benefits)

Coverage of Drugs under Part B versus Part D

Policy 1303

02/01/2013 Introduced

The administrative burdens resulting from certain medications being eligible for coverage either under Part B or Part D has created confusion, delay and expense for all involved: beneficiaries, Part D plans, providers and the Medicare program itself. The Academy of Managed Care Pharmacy suggests that remedial legislative action on this issue is one of the most important corrective actions that Congress can take as it addresses modifications to the current Medicare Part D program. It is also an issue that can have a dramatic, valuable impact on beneficiary health and well-being, as well as taxpayer savings.

### AMCP Recommends:

- 1. The Academy recommends that the following drugs, which can be self-administered, be moved from Part B, where they are covered in certain situations, to Part D coverage in all situations:
  - Oral chemotherapeutics
  - Oral anti-emetics
  - Inhalation and blood glucose monitoring DME supply drugs
  - Immunosuppressants
- 2. To decrease confusion, all vaccines should be covered under the same part of the Medicare benefit—in this case Part B.
- 3. The Academy recommends that Medicare Part D plans that have made a coverage determination that can be demonstrated to have

been in good faith, and after exercising due diligence, be exempt from legal jeopardy.

(See AMCP'S Medicare Part D Concept Series – Coverage of Drugs under Part B versus Part D)

Government Negotiation of Prescription Drug Prices

Policy 1304

02/01/2013 Introduced

The Academy of Managed Care Pharmacy (AMCP) opposes legislation that would allow or require the federal government to negotiate prescription drug prices on behalf of Medicare Part D plan sponsors. The Academy supports the current structure of the Part D benefit that relies on the concept that drug price concessions are best achieved by negotiations by participating drug plan sponsors who themselves are motivated by the competitive need to provide the most cost-effective and clinically appropriate drug benefits possible. AMCP believes proposals to repeal the noninterference provision would introduce consequences that must be thoughtfully considered before action is taken.

(See AMCP'S Medicare Part D Concept Series – Government Negotiation of Prescription Drug Prices)

The Competitive Model

Policy 1305

02/01/2013 Introduced

The Academy of Managed Care Pharmacy (AMCP) supports the continuation of the competitive model for the Medicare Part D program. The Academy supports legislation and regulation that will allow proven private sector best practices to be applied in the public sector. The Academy will oppose changes to the drug benefit program that would undermine the use of effective managed care strategies. It will oppose changes that would dilute the competitive structure currently being used for the delivery of the Medicare drug benefit. Additionally, program elements that hinder the use of pharmacy benefit best practices from the private sector should be eliminated.

(See AMCP'S Medicare Part D Concept Series – *The Competitive Model*)

Maximum Allowable Cost (MAC) Pricing

Policy 1301

10/01/2013 Introduced

AMCP believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care Legislation that allows the government to dictate reimbursement terms of a private contract between a payer and a pharmacy or that mandates that the payer disclose proprietary pricing methodology is not an appropriate focus of government regulation. Further, AMCP believes that competitive negotiations between parties are more likely to provide fair and equitable reimbursement on drugs dispensed. AMCP does not support the intervention of government into private contracts to require payers to advise pharmacies on where to purchase their drugs; that is an unnecessary and inappropriate intrusion into the private arrangements of a pharmacy with its supplier. This type of government mandate takes away the incentive for a pharmacy to make wise purchasing decisions. The payers and consumers will not benefit from a system of government mandated payments to a private entity; rather it will decrease competition and further drive up the cost of the prescription drug benefit.

(See also AMCP Where We Stand Position Statement – Government Regulation of Prescription Drug Prices)

**Preferred Pharmacy Networks** 

Policy 1401

07/29/2014 Introduced

The Academy of Managed Care Pharmacy (AMCP) supports the ability of health plans to offer preferred pharmacy networks for their enrollees as a way of providing additional options and cost savings without any diminishment of quality or patient access. Preferred pharmacy networks represent an important tool and innovation in managed care pharmacy benefits. The Academy supports the continued use of these programs as a beneficial way to maintain quality of care, access and cost effectiveness to the pharmacy benefit.

Medicare Part D Quality Measures

Policy 1403

10/07/2014 Introduced

The Academy recognizes the essential role of pharmacists and plans in improving the quality of care provided to patients and supports a measure development process which allows for timely integration of evidence-based medicine and feedback from stakeholders. AMCP additionally emphasizes the need to align measures across programs to promote consistency, economic efficiency, and quality across the health care system.

(See also AMCP Future of Medicare Part D Statement - *Medicare Part D Quality Measures*)

## **MEDICATION SAFETY**

Pharmacist's Role in Detecting and Reporting Adverse Drug Events (ADEs)

Policy 9921

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Reapproved AMCP believes that pharmacists have a responsibility to identify potential and actual drug-related problems, resolve actual drug-related problems, and prevent potential drug-related problems. Therefore, AMCP encourages pharmacists to take responsibility in promoting the development, maintenance, and ongoing evaluation of programs to reduce the risk of ADEs in enrolled populations and individuals through detecting, reporting, and assessing any suspected ADEs. AMCP also encourages pharmacists to take a leadership role within managed health care systems to establish a non-threatening, non-punitive, confidential work place environment that encourages pharmacists and other health care professionals to report actual and suspected adverse drug events in a timely manner.

Medication Errors and Risk Management

Policy 0104

03/01/2001 Introduced 02/01/2006 Reapproved 12/01/2010 Revised

OTC Brand Name Confusion

Policy 0106

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Reapproved

Recommendations to Reduce Medication Errors

Policy 0109

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Revised AMCP encourages pharmacists and other health care practitioners to be involved in the risk management procedures of a health care system so that they may employ preventative strategies for medication errors, review medication error occurrences and implement corrective actions, and assess a medication use system's susceptibility to medication errors.

AMCP is concerned that a distinct brand name on an OTC product does not always refer to the same active ingredient(s). This inconsistent relationship between brand name and ingredients may be confusing to some patients and may lead to medication errors and adverse events. AMCP believes that the naming approach should be changed to avoid this confusion. In conjunction with pharmacists, physicians, and other health care professionals, product names and packaging should be adopted and designed to minimize confusion and prevent adverse outcomes.

To reduce the number and severity of medication errors in all practice settings, AMCP believes that colleges, schools, and state associations of pharmacy, nursing and medicine; national professional associations; managed health care systems; thirdparty-payers; pharmaceutical manufacturers; regulators; employers; and consumers must mount a nationwide campaign for medication error reporting and prevention. AMCP encourages these entities and individuals to endorse and adopt the recommendations developed by the National Coordinating Council for Medication Error Reporting and Prevention. AMCP encourages all health care professionals, care givers, and patients, to take an active role in efforts to identify, monitor, evaluate and prevent medication errors, through the development of medication use processes with a focus on identifying, preventing and correcting

	errors and establishing a non-threatening, non-punitive, confidential work place environment that encourages pharmacists and other health care professionals to report medication errors and near misses in a timely manner.
Regulation of Dietary Supplements	AMCP advocates the modification of the Dietary Supplement Health and Education Act or enactment of other legislation for all products falling under the Act, requiring that dietary supplement
Policy 0110	manufacturers provide evidence of product efficacy and safety, label products with full disclosure of all components (including
03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Reapproved	source, strength, and recommendations for use), and implement a mechanism to remove promptly unsafe or ineffective products from the marketplace. AMCP encourages expansion of the National Institutes of Health Office of Dietary Supplement's Internet site to include reports of adverse health events from manufacturers, health care professionals, consumers, the Food and Drug Administration, and the Center for Food Safety and Applied Nutrition.
Specialty Pharmaceuticals	AMCP encourages pharmacists to take a leadership role in their
Policy 0112	practice site for proper use and administration of specialty pharmaceuticals, which includes care management, storage, control, safe handling, preparation, administrative procedures, and
03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised	distribution. Specialty pharmaceuticals are generally high-cost medications, usually prescribed for people with complex or chronic medical conditions, or they may be medications that typically exhibit one or more of the following characteristics:  • drugs that are injected or infused, however, some may be
	taken by mouth;  • drugs that have unique monitoring, storage or shipment requirements; and
	<ul> <li>drugs that require additional education and supports from a health care professional</li> </ul>
Disposal of Needles and Syringes	AMCP supports the development and implementation of safe systems and procedures for the disposal of used needles and syringes by patients outside of health care facilities.
Policy 0113	
11/01/2001 Introduced 11/01/2005 Reapproved 11/01/2009 Reapproved	

02/21/2018 Reapproved

Restricted Distribution of Pharmaceuticals  Policy 0119  11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Revised	AMCP generally opposes any restrictions on the distribution of pharmaceutical products either by the pharmaceutical industry or as a condition for FDA-approval. AMCP acknowledges that circumstances may occur with the use of specific medications that require special distribution, monitoring and management processes. As long as,  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 physicians, 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 cost 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; 7. The requirements do not interfere with the professional practice of pharmacists, physicians, or other appropriately qualified healthcare professionals.
	(The enumerated principles are drawn from ASHP <i>Principles for Restricted Distribution Systems</i> )
Prescription Drug Importation  Policy 0302  02/01/2003 Introduced 02/01/2008 Revised 02/01/2013 Revised	Legislation that would permit the importation of prescription drugs presents potential patient safety issues. Allowing the importation of prescription drugs raises a challenge to ensure that quality assurance standards have been maintained. AMCP believes that more conclusive data are needed as to the likely impact of importation. AMCP will oppose legislation that would allow the importation of prescription drugs for sale in the United States until more conclusive data are available as to its likely impact.  (See also AMCP Where We Stand Position Statement – <i>Prescription Drug Importation</i> )
Redispensing of Unused	AMCP supports programs for the return, reuse and payment credit
Medications	of unused medications from state programs, long-term care facilities, and other medical facilities.
Policy 0703	Authority to redispense medication should only be permitted when:
06/01/2007 Introduced	Unused medication has not left the supervision of a health     sare professional or designated representative.

care professional or designated representative

- Unused medication is in the original sealed packaging (e.g., unit of use packaging)
- Unused medication has been properly stored
- Unused medication has not expired

In addition, such programs should:

- Provide an equal standard of care for all patients
- Decrease waste
- Decrease medication costs for both patient and benefit providers
- Minimize environmental impact of discarded medication
- Ensure the integrity and safety of the product
- Protect the privacy of the original recipient
- Comply with state and federal requirements

Biosimilar Drug Therapies AMCP supports an abbreviat

Policy 0802

06/01/2008 Introduced 04/01/2012 Revised 10/01/2012 Reapproved AMCP supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies. In order to strike an appropriate balance between bringing safe and effective drugs to market and maximizing patient access to affordable drugs, the FDA should determine on a case-by-case basis the need for additional clinical studies prior to approval, as well as any post-marketing studies. Manufacturers of approved biosimilars should be allowed to use the same government-approved/international non-proprietary name as the reference product. The FDA should also provide clear rules for the designation of a biosimilar product as interchangeable with a reference product, similar to the current "AB" ratings used for small-molecule chemical drugs. A designation of interchangeability should not be a requirement as a condition for approval of a biosimilar product.

(See AMCP Where We Stand Position Statement – *Biosimilar Drug Therapies*)

**Drug Utilization Management** 

Policy 0905

06/01/2009 Introduced 12/01/2013 Revised

AMCP supports drug utilization management tools and formal prospective, concurrent or retrospective programs which utilize the principals of evidence based medicine to consider clinical appropriateness, cost effectiveness, patient safety and patient outcomes. Drug utilization management works ideally when coupled with a quality assurance strategy. Applications of drug utilization management may include, but are not limited to, refining practice guidelines, supporting medication therapy management, developing prior authorization and dose optimization criteria, benefit design, and channel management strategies.

# **MEDICATION THERAPY MANAGEMENT**

Collaborative Drug Therapy Management

Policy 9903

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 06/01/2011 Revised 10/01/2012 Reapproved AMCP supports the concept of collaborative drug therapy management (CDTM) a formal partnership between a pharmacist and a prescriber that allows the pharmacist to manage a patient's drug therapy. CDTM, also referred to a collaborative practice, allows pharmacists to use their unique skills and abilities to complement other types of care provided by collaborating professionals to optimize patient outcomes. When pharmacists practice under CDTM agreements, equivalent or superior levels of health care services and outcomes are demonstrated when compared with settings where pharmacists were not involved.

(See AMCP Where We Stand Position Statement – *Collaborative Drug Therapy Management*)

Disease Management

Policy 9907

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Revised AMCP supports disease management as the concept of reducing health care costs, closing gaps in care, and improving quality of life for individuals with chronic conditions by preventing or minimizing the effects of the disease through integrated medical and pharmacy management. Disease management programs are designed to improve health outcomes and reduce associated costs from avoidable complications by identifying and treating chronic conditions more quickly and effectively, and improving appropriate medication use and adherence, thus slowing the progression of those diseases. AMCP recognizes that, as trained medication management specialist, the pharmacist has a leadership role to play in the collaborative development, implementation and improvement of disease management programs.

(See AMCP Concepts in Managed Care Pharmacy - *Disease Management*)

Evidence-based Clinical Practice Guidelines

Policy 0007

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/21/2018 Revised AMCP advocates direct involvement of pharmacists in the development, evaluation, and implementation of evidence-based clinical practice guidelines that focus on an interdisciplinary team approach to patient care.

Health Care Team Approach to Optimal Therapeutic Outcomes

Policy 0014

AMCP believes that achieving optimal therapeutic outcomes for each patient is a shared responsibility of the health care team. AMCP further supports the active role of the pharmacist in the development, implementation and monitoring of therapeutic plans,

02/01/2000 Introduced 02/01/2005 Reapproved 02/01/2010 Reapproved 04/07/2015 Revised which include provider communication and assisting patients to become informed decision makers to improve adherence with their prescribed therapeutic plan.

Pharmacist-Patient Communication

Policy 0020

02/01/2000 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 04/07/2015 Revised AMCP recognizes that patient education is a fundamental element of pharmaceutical care. Further, AMCP believes that pharmacists have a professional obligation to provide patients with accurate, understandable information to promote safe and effective medication use. In order to deliver information that will foster positive health care outcomes, pharmacists must recognize the unique needs of each individual patient or patient population. Therefore, the pharmacist must exercise professional judgment in determining the best way to deliver essential patient information: verbally, in writing, electronically, through use of pictographs or through the internet or through a caregiver or guardian. When faceto-face pharmacist-patient communication is appropriate, pharmacy facilities must allow for convenient, comfortable, and private conversation, supplemented by written, printed, or other material that is best suited to the patient's specific needs. These principles also apply to virtual pharmacist-patient communication, where applicable.

State Pharmacy Practice Act Revisions

Policy 0026

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved

Medication Use Outside of the Home

Policy 0105

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Reapproved AMCP recommends enactment of state pharmacy practice act revisions enabling pharmacists to fulfill their roles as health care providers, drug therapy managers, and full members of the patient care team.

AMCP recognizes the role of pharmacists in improving the safe and appropriate use and storage of medications in all environments. Institutions, such as hospitals and long-term care facilities, have regulations and requirements for administration and storage of medications. However, many entities like schools, camp, and group homes, do not have regulations or requirements regarding the handling of medications in their facilities. AMCP recommends that pharmacists be actively involved in the development of procedures for safe and appropriate medication use and storage by working with parents and appropriate personnel at schools, camps and group homes to improve medication use policies and procedures within their specific environment.

#### **Pharmacogenomics** AMCP supports further research and assessment of the economic, clinical, and humanistic impact of pharmacogenomics on managed Policy 0107 care pharmacy practice. AMCP supports the pharmacist's leadership role in the review and evaluation of scientific evidence and the 03/01/2001 Introduced subsequent development of pharmaceutical care processes 11/01/2005 Reapproved involving these therapies through collaboration with other health 11/01/2009 Revised care practitioners and consumer organizations. Pharmacy and 02/01/2014 Revised Therapeutics Committees in collaboration with Health Technology Assessment committees should be involved in the decision-making process related to coverage of genetic tests and utilization management strategies. Pharmacy Benefits for the AMCP supports the development of systems to ensure access to Uninsured/Underinsured pharmacists and pharmaceuticals for all patients, regardless of income or insured status. Policy 0118 11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Reapproved **Continuous Quality** AMCP supports development and implementation of continuous Improvement quality improvement programs throughout the medication use process, and encourages all practitioners to establish performance Policy 0301 improvement processes in their various practice settings. 02/01/2003 Introduced 02/01/2008 Reapproved 10/01/2012 Reapproved 02/21/2018 Revised Pharmacists' Role in Promoting AMCP believes that patient lifestyle choices play a significant role in Lifestyle Modifications to the success or failure of treatment regimens. Patients who make Improve Health Outcomes positive lifestyle choices have a greater probability of reaching treatment goals (e.g., smoking cessation for patients with COPD; Policy 0502 diet and exercise for patients with diabetes). Pharmacists in all practice settings should educate patients to pursue recommended 02/01/2005 Introduced lifestyle modifications as part of their prescribed treatment 02/01/2010 Reapproved regimen, in order for patients to achieve the best possible health 04/07/2015 Revised outcome. Patient Care Services Provided AMCP believes that the pharmacist and health care practitioners, as by a Pharmacist the medication management professional, has the training and expertise to provide pharmaceutical care services that improve Policy 0601 patient outcomes and reduce health care costs. AMCP encourages pharmacists to lead collaborative efforts in the development and 02/01/2006 Introduced implementation of pharmaceutical care plans. AMCP supports

12/01/2010 Revised

adequate compensation for pharmaceutical care services provided

by pharmacists or other licensed health care providers that demonstrate value to practitioners, patients and payers.

Medication Reconciliation/Transitions of Care

Policy 0702

04/01/2007 Introduced

AMCP supports pharmacists in their unique role in ensuring the continuity of a patient's medication therapy regimen when moving among diverse health care settings. Pharmacists analyze and communicate information about the safety, effectiveness and outcomes of drug therapy to other health care providers to ensure appropriate continuity of drug therapy. Additionally, pharmacists can best serve patients by providing consultation that gives them the ability to understand and remain adherent to medication therapy regimens as the patient moves from one setting to another.

(See AMCP Framework for Quality Drug Therapy)

Medication Therapy Management (MTM) Programs

Policy 0906

06/01/2009 Introduced 02/01/2014 Revised

**Provider Status for Pharmacists** 

Policy 1201

06/01/2013 Introduced 03/27/2017 Revised 07/19/2018 Revised 10/22/2018 Revised AMCP recommends that medication therapy management (MTM) programs be designed based on the needs of identified populations of a plan, utilizing appropriate patient selection criteria and interventions to meet the needs of individual members and optimize medication use. Emphasis should be placed on coordination of care for the patient, and integration of MTM programs, disease management and medical management programs, when possible, to effectuate enhanced patient outcomes. MTM programs should identify appropriate outcomes and design measurements to assess the outcomes while maintaining appropriate documentation and results. MTM programs should be evaluated and revised on a continuing basis to ensure that appropriate quality and continued value is maintained.

The Academy of Managed Care Pharmacy (AMCP) supports the recognition of pharmacists as providers under the Social Security Act. Pharmacists provide measurable improvements in healthcare outcomes and patientsatisfaction and reduce overall healthcare expenditures. AMCP strongly believes the formal recognition of pharmacists as health care providers will increase their contribution to address primary healthcare needs, including medication administration, as part of collaborative healthcare with fewer barriers.

(See AMCP Where We Stand Position Statement – *Provider Status for Pharmacists*)

Medicare Part D Quality The Academy recognizes the essential role of pharmacists and plans Measures in improving the quality of care provided to patients and supports a measure development process which allows for timely integration Policy 1403 of evidence-based medicine and feedback from stakeholders. AMCP additionally emphasizes the need to align measures across 10/07/2014 Introduced programs to promote consistency, economic efficiency, and quality across the health care system. (See AMCP Future of Medicare Part D Statement – Medicare Part D **Quality Measures**) The Academy of Managed Care Pharmacy (AMCP) supports the Medication Synchronization concept of medication synchronization as one tool that may Policy 1501 improve adherence. Prescription drug therapy provides a tremendous value to the overall healthcare system and that value 02/10/2015 Introduced is only realized when medication therapies are taken by patients as prescribed. AMCP supports continued industry development and rollout of medication synchronization programs and believes that best practices currently being developed will benefit patients and payers. Therefore AMCP will oppose legislation that mandates medication synchronization and requires a specific government

(See AMCP Where We Stand Position Statement – *Medication Synchronization*.)

framework as an unnecessary barrier to best practices.

### **PAIN MANAGEMENT**

Pain Management in supports of End-of-Life Care

Policy 9917

11/01/1999 Introduced 03/01/2004 Revised 12/01/2008 Reapproved 10/01/2012 Reapproved AMCP opposes federal and state legislative and regulatory provisions that would foster inadequate pain treatment for patients and lessen the ability of patients to receive comprehensive end-of-life care. Further, AMCP believes that care for the dying patient is an integral part of the pharmacist's provision of pharmaceutical care.

**Substance Abuse Programs** 

Policy 0008

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/21/2018 Revised AMCP supports the involvement of pharmacists in the development and promotion of programs that prevent substance abuse and educate about substance use disorder. AMCP recommends pharmacists monitor drug use to identify cases of misuse or abuse and work with providers and patients on the best evidence-based, therapeutic intervention and monitoring plan.

Management of Opioids

Policy 1306

06/01/2013 Introduced 04/23/2018 Revised

The Academy of Managed Care Pharmacy (AMCP) is focused on identifying the improper use of opioids and the enormous costs to Society that go beyond traditional health care costs. AMCP wants to assure the proper management of patients suffering from uncontrolled pain, cancer and those who are terminally ill, while limiting the abuse and diversion of opioids. Policies that address the opioid epidemic must strike a balance that maintains appropriate access for those patients.

AMCP advocates for sensible changes to existing laws at the federal and state level to authorize implementation of patient safety programs such as requiring electronic prescribing (e-prescribing) of opioids, updating Risk Evaluation and Mitigation Strategy (REMS) and continuing medication education for prescribers. AMCP also supports the ongoing development and implementation of prescription drug monitoring programs (PDMPs) and expanding access to PDMPs to include health plans and pharmacy benefit managers (PBMs). Giving those organization access to PDMPs will enhance their ability to recognize and assist patients that may be abusing opioids while identifying those patients that may be a source of diversion.

AMCP encourages strategies addressing overdose education including naloxone distribution programs as well as the proper disposal of unused prescription opioids and Drug Takeback Days as tools to combat diversion in communities across the country. AMCP supports a legislative and regulatory framework that increases the ability of health plans and PBMs to effectively manage the use of opioids, in a clinically appropriate manner and limit the

potential for abuse, using managed care strategies in collaboration with others in the health care community.

006/01/2013 Introduced\*

04/23/2018 Revised (\*subject originally included policy on abuse deterrent and tamper resistant formulations, those subjects now included in Policy 1802)

Abuse Deterrent and Tamper Resistant Formulations

Policy 1802

04/23/2018 Introduced

AMCP encourages the U.S. Food and Drug Administration (FDA) to use its expertise to establish standards for the definition of "abuse-deterrent" and "tamper resistant." The Agency should also require that manufacturers of those products undertake reasonable post-marketing surveillance studies that will help assess the impact of the products on both the abuse of the specific product, as well as overall rates of abuse. Because opioids may vary in their clinical effectiveness and abuse potential, AMCP supports expanding the ability of health plans to clinically manage these products. Therefore, AMCP does not support mandating the use of "abuse deterrent" and "tamper resistant products." AMCP maintains that such products are not clinically necessary for all patients.

### **PATIENT CONFIDENTIALITY**

**Patient Confidentiality** 

Policy 9918

11/01/1999 Introduced 03/01/2001 Revised 06/01/2003 Revised 02/01/2008 Revised 10/01/2012 Reapproved AMCP supports protection of patient confidentiality and endorses the responsible and sensible use of patient identifiable medical and prescription drug information by authorized physicians, pharmacists, other health care professionals, and researchers to enhance the effectiveness and quality of health care service. AMCP believes that state and federal statutes and regulations that pertain to the use of patient identifiable information must not hinder the effective administration of pharmacy benefits and impede patient protections already in place. Managed health care systems should use patient identifiable information only when it is essential to assure or improve safe, accurate and efficient delivery and coordination of health care services.

(See AMCP Where We Stand Position Statement – *Patient Confidentiality*).

Patient Rights and Responsibilities

Policy 9919

11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP recognizes and supports the concept that all consumers should have certain health care rights that assure confidentiality of health care services, provide access to high quality health care, and allow access to information with which they may make informed decisions regarding their health care choices. However, inherent with these rights is the responsibility of each person to implement lifestyle activities that promote optimal responses to health care treatment, to follow medical advice and to become knowledgeable of his or her pharmacy benefit health care options.

(See AMCP Where We Stand Position Statements – *Patient Rights and Responsibilities*, and *Patient Confidentiality*)

Pharmacist-Patient Communication

Policy 0020

02/01/2000 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 04/07/2015 Revised AMCP recognizes that patient education is a fundamental element of pharmaceutical care. Further, AMCP believes that pharmacists have a professional obligation to provide patients with accurate, understandable information to promote safe and effective medication use. In order to deliver information that will foster positive health care outcomes, pharmacists must recognize the unique needs of each individual patient or patient population. Therefore, the pharmacist must exercise professional judgment in determining the best way to deliver essential patient information: verbally, in writing, electronically, through use of pictographs or through the internet or through a caregiver or guardian. When faceto-face pharmacist-patient communication is appropriate, pharmacy facilities must allow for convenient, comfortable, and private conversation, supplemented by written, printed, or other material that is best suited to the patient's specific needs. These principles also apply to virtual pharmacist-patient communication, where applicable.

Policy Collaboration to Achieve Optimal Patient Outcomes

Policy 0023

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved

Electronic Health Information Technology

Policy 0704

02/01/2008 Introduced 10/01/2012 Reapproved AMCP supports collaboration with other pharmacy, health care, and consumer organizations in public and professional policy development where such policy development promotes improved patient outcomes and quality of care.

AMCP supports the implementation and expanded use of electronic health information technology, including electronic health records and electronic prescribing, provided that there are appropriate mechanisms in place to protect the privacy of patients. Electronic health information technology promises improvement in quality and efficiency, data collection and reporting and may help restrain cost increases. Use of this technology will require national standards ensuring patient privacy and system interoperability that are developed in concert with the federal government and patient, provider and payer groups.

(See AMCP Where We Stand Position Statement – *Electronic Health Information Technology*)

AMCP supports the use of prescription information, whether individually identifiable by patient or prescriber or aggregated without identifying specific individuals, in a responsible manner. When used properly, this information can help promote responsible prescription drug use, protect patient safety and reduce overall health care costs. However, AMCP does not support the use, sale or purchase of this information with the intent to use it for marketing or other commercial purposes.  (See AMCP Where We Stand Position Statement – Appropriate Uses
of Prescription Information by Managed Care Organizations)
Appropriate transparency throughout the health care delivery system can help all parties involved – managed care organizations, payers, providers, and patients – make informed decisions
regarding the use of valuable health care resources. These decisions can help promote positive health outcomes protect patient safety
and ensure the affordability of a prescription drug benefit. While certain information should remain confidential in order to ensure a competitive marketplace, AMCP supports efforts to promote transparency throughout the entire health care system.
(See AMCP Where We Stand Position Statement – <i>Transparency Within Health Care</i> )
AMCP supports the collaboration of pharmacists, managed health
care systems, employers, payers, professional organizations, and legislative and regulatory organizations in the development of
continuous quality improvement mechanisms to assess, ensure, and promote competence of pharmacists. Pharmacists have a
responsibility to identify areas for focused education and/or
experiential training and to reassess their competence in these
areas.
AMCP supports the Food and Drug Administration's (FDA) position
that when an FDA-approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be
assured that they will see the same clinical results and safety profile as with the equivalent brand name product. Therefore, NTI drugs
should not be considered as a separate category for purposes of

03/01/2004 Reapproved 12/01/2008 Reapproved

consultation with prescribers, should have the right to use their professional judgment and knowledge of the available scientific information in determining when to substitute a generic product.

(See AMCP Where We Stand Position Statement – *Interchange of Narrow Therapeutic Index (NTI) Drugs*)

AMCP recognizes the role of pharmacists in improving the safe and

appropriate use and storage of medications in all environments.

Medication Use Outside of the Home

Home

Institutions, such as hospitals and long-term care facilities, have regulations and requirements for administration and storage of medications. However, many entities like schools, camp, and group homes, do not have regulations or requirements regarding the handling of medications in their facilities. AMCP recommends that pharmacists be actively involved in the development of procedures for safe and appropriate medication use and storage by working

12/01/2010 Revised pharmacis 04/07/2015 Reapproved for safe a with pare

with parents and appropriate personnel at schools, camps and group homes to improve medication use policies and procedures within their specific environment.

Safe Medication Disposal

03/01/2001 Introduced

02/01/2006 Revised

Policy 1803

Policy 0105

02/21/2018 Introduced

AMCP supports the development and utilization of programs to assist in the safe disposal of unused or unwanted medications, such as in-house disposal, use of authorized collectors, and drug takeback days, to help reduce harm from unintended use, misuse, or accidental exposure.

AMCP supports the use of pharmacy technicians under the

#### **PHARMACY TECHNICIANS**

Pharmacy Technicians in supports of Managed Care Pharmacists

supervision of a licensed pharmacist. Highly skilled and knowledgeable pharmacy technicians allow managed care pharmacists to focus on providing optimal pharmaceutical care.

Policy 9924

11/01/1999 Introduced 03/01/2004 Revised 12/01/2008 Revised 10/01/2012 Reapproved

#### **Pharmacist Recovery Programs**

Policy 0021

02/01/2000 Introduced 02/01/2003 Revised 02/01/2008 Revised 10/01/2012 Reapproved AMCP supports the establishment by state boards of pharmacy of counseling, treatment, prevention, and rehabilitation programs for pharmacists, pharmacy technicians and student pharmacists who are subject to physical or mental impairment due to the influence of drugs — including alcohol — or other causes, when such impairment has potential to adversely impact their abilities to function properly in a professional capacity. AMCP supports the empowerment of state boards of pharmacy to use discretionary powers in determining employment waiver requests relating to the licensure of impaired pharmacists and pharmacy technicians.

Pharmacy Technician Education, Training, Certification, and Registration AMCP supports standardized education, training, certification and registration of pharmacy technicians to further protect public health and safety and assist pharmacists in providing optimal medication therapy outcomes for patients.

Policy 0907

11/01/2009 Introduced

Safe Medication Disposal

Policy 1803

02/21/2018 Introduced

AMCP supports the development and utilization of programs to assist in the safe disposal of unused or unwanted medications, such as in-house disposal, use of authorized collectors, and drug takeback days, to help reduce harm from unintended use, misuse, or accidental exposure.

### PRODUCT PACKAGING AND LABELING

Drug Names, Labels, and Packaging

Policy 9908

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Reapproved AMCP encourages drug manufacturers and the FDA to work with pharmacists, physicians, other health care professionals and professional organizations to design and adopt drug names, labeling, and packaging that will avoid confusion and help prevent medication errors.

Regulation of Dietary Supplements

Policy 0110

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Reapproved AMCP advocates the modification of the Dietary Supplement Health and Education Act or enactment of other legislation for all products falling under the Act, requiring that dietary supplement manufacturers provide evidence of product efficacy and safety, label products with full disclosure of all components (including source, strength, and recommendations for use), and implement a mechanism to remove promptly unsafe or ineffective products from the marketplace. AMCP encourages expansion of the National Institutes of Health Office of Dietary Supplement's Internet site to include reports of adverse health events from manufacturers, health care professionals, consumers, the Food and Drug Administration, and the Center for Food Safety and Applied Nutrition.

# **PROVIDER STATUS**

Collaborative Drug Therapy Management

Policy 9903

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 06/01/2011 Revised 10/01/2012 Reapproved AMCP supports the concept of collaborative drug therapy management (CDTM) a formal partnership between a pharmacist and a prescriber that allows the pharmacist to manage a patient's drug therapy. CDTM, also referred to a collaborative practice, allows pharmacists to use their unique skills and abilities to complement other types of care provided by collaborating professionals to optimize patient outcomes. When pharmacists practice under CDTM agreements, equivalent or superior levels of health care services and outcomes are demonstrated when compared with settings where pharmacists were not involved.

(See AMCP Where We Stand Position Statement – *Collaborative Drug Therapy Management*).

#### Disease Management

Policy 9907

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Revised 10/01/2012 Revised AMCP supports disease management as the concept of reducing health care costs, closing gaps in care, and improving quality of life for individuals with chronic conditions by preventing or minimizing the effects of the disease through integrated medical and pharmacy management. Disease management programs are designed to improve health outcomes and reduce associated costs from avoidable complications by identifying and treating chronic conditions more quickly and effectively, and improving appropriate medication use and adherence, thus slowing the progression of those diseases. AMCP recognizes that, as trained medication management specialist, the pharmacist has a leadership role to play collaborative development, implementation in improvement of disease management programs.

(See AMCP Concepts in Managed Care Pharmacy – *Disease Management*).

Pharmacist's Role in Immunizations

Policy 9923

11/01/1999 Introduced 03/01/2001 Revised 02/01/2006 Reapproved 10/01/2010 Reapproved AMCP recognizes that pharmacists have a responsibility to the public and to individual patients to promote disease prevention through their involvement in community and employer-based programs that promote appropriate immunization to all citizens, especially those at risk. AMCP supports federal and state legislative and regulatory provisions that give pharmacists the authority to administer immunizations. Further, AMCP affirms that schools and colleges of pharmacy should include education and training concerning the promotion and administration of immunizations in their curricula.

Evidence-based Clinical Practice Guidelines

AMCP advocates direct involvement of pharmacists in the development, evaluation, and implementation of evidence-based

Policy 0007  02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/21/2018 Revised	clinical practice guidelines that focus on an interdisciplinary team approach to patient care.
Health Care Team Approach to Optimal Therapeutic Outcomes Policy 0014 02/01/2000 Introduced 02/01/2005 Reapproved 02/01/2010 Reapproved 04/07/2015 Revised	AMCP believes that achieving optimal therapeutic outcomes for each patient is a shared responsibility of the health care team. AMCP further supports the active role of the pharmacist in the development, implementation and monitoring of therapeutic plans, which include provider communication and assisting patients to become informed decision makers to improve adherence with their prescribed therapeutic plan.
Pharmacist-Patient Communication  Policy 0020  02/01/2000 Introduced 02/01/2005 Revised 02/01/2010 Reapproved 04/07/2015 Revised	AMCP recognizes that patient education is a fundamental element of pharmaceutical care. Further, AMCP believes that pharmacists have a professional obligation to provide patients with accurate, understandable information to promote safe and effective medication use. In order to deliver information that will foster positive health care outcomes, pharmacists must recognize the unique needs of each individual patient or patient population. Therefore, the pharmacist must exercise professional judgment in determining the best way to deliver essential patient information: verbally, in writing, electronically, through use of pictographs or through the internet or through a caregiver or guardian. When face-to-face pharmacist-patient communication is appropriate, pharmacy facilities must allow for convenient, comfortable, and private conversation, supplemented by written, printed, or other material that is best suited to the patient's specific needs. These principles also apply to virtual pharmacist-patient communication, where applicable.
Pharmacy CPT Codes  Policy 0022  02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/01/2014 Reapproved	AMCP supports the use and expansion of pharmacy-specific codes listed in the American Medical Association's Physicians' Current Procedural Terminology (CPT) coding structure to assist pharmacists in coding for their professional services.
State Pharmacy Practice Act Revisions Policy 0026 02/01/2000 Introduced	AMCP recommends enactment of state pharmacy practice act revisions enabling pharmacists to fulfill their roles as health care providers, drug therapy managers, and full members of the patient care team.

# 02/01/2005 Reapproved 11/01/2009 Reapproved

Medication Use Outside of the Home

Policy 0105

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Reapproved

Pharmacy Benefits for the Uninsured/Underinsured AMCP supports the development of systems to ensure access to pharmacists and pharmaceuticals for all patients, regardless of

income or insured status.

Policy 0118

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Reapproved AMCP recognizes the role of pharmacists in improving the safe and appropriate use and storage of medications in all environments. Institutions, such as hospitals and long-term care facilities, have regulations and requirements for administration and storage of medications. However, many entities like schools, camp, and group homes, do not have regulations or requirements regarding the handling of medications in their facilities. AMCP recommends that pharmacists be actively involved in the development of procedures for safe and appropriate medication use and storage by working with parents and appropriate personnel at schools, camps and group homes to improve medication use policies and procedures within their specific environment.

Pharmacists' Role in Promoting Lifestyle Modifications to Improve Health Outcomes

Policy 0502

02/01/2005 Introduced 02/01/2010 Reapproved 04/07/2015 Revised AMCP believes that patient lifestyle choices play a significant role in the success or failure of treatment regimens. Patients who make positive lifestyle choices have a greater probability of reaching treatment goals (e.g. smoking cessation for patients with COPD; diet and exercise for patients with diabetes). Pharmacists in all practice settings should educate patients to pursue recommended lifestyle modifications as part of their prescribed treatment regimen, in order for patients to achieve the best possible health outcome.

Patient Care Services Provided by a Pharmacist

Policy 0601

02/01/2006 Introduced 12/01/2010 Revised

AMCP believes that the pharmacist and health care practitioners, as the medication management professional, has the training and expertise to provide pharmaceutical care services that improve patient outcomes and reduce health care costs. AMCP encourages pharmacists to lead collaborative efforts in the development and implementation of pharmaceutical care plans. AMCP supports adequate compensation for pharmaceutical care services provided by pharmacists or other licensed health care providers that demonstrate value to practitioners, patients and payers.

Medication
Reconciliation/Transitions of Care

Policy 0702

04/01/2007 Introduced

AMCP supports pharmacists in their unique role in ensuring the continuity of a patient's medication therapy regimen when moving among diverse health care settings. Pharmacists analyze and communicate information about the safety, effectiveness and outcomes of drug therapy to other health care providers to ensure appropriate continuity of drug therapy. Additionally, pharmacists can best serve patients by providing consultation that gives them the ability to understand and remain adherent to medication therapy regimens as the patient moves from one setting to another.

(See AMCP Framework for Quality Drug Therapy)

Behind-the-Counter Drugs

Policy 0903

06/01/2009 Introduced

AMCP supports the establishment of a class of drugs that would allow consumers, with the intervention of a pharmacist, to purchase certain medications without a prescription. The establishment of a behind-the-counter (BTC) classification would grant patients access to necessary medications while being counseled by a pharmacist to ensure that the patient meets certain criteria prior to dispensing and to provide education on proper use and monitoring. AMCP supports the establishment of a third class of BTC drugs if the following conditions are met:

- Medications selected for BTC status must provide a benefit to the public
- Decisions on which drugs are selected for BTC status must be based on clinical effectiveness and safety
- Standardized processes for ordering and dispensing of BTC drugs must be established
- Pharmacists must be required to perform clinical evaluation and interventions before dispensing BTC drugs
- Pharmacist training requirements must be based on knowledge and skills required to interpret objective clinical data and to apply selection criteria in order to dispense BTC products
- Patient health information must be protected
- Program oversight requirements must be developed

(See AMCP Where We Stand Position Statement – *Behind-the-Counter Drugs*)

Medication Therapy
Management (MTM) Programs

Policy 0906

06/01/2009 Introduced 02/01/2014 Revised

AMCP recommends that medication therapy management (MTM) programs be designed based on the needs of identified populations of a plan, utilizing appropriate patient selection criteria and interventions to meet the needs of individual members and optimize medication use. Emphasis should be placed on coordination of care for the patient, and integration of MTM programs, disease management and medical management programs, when possible, to effectuate enhanced patient outcomes. MTM programs should identify appropriate outcomes and design measurements to assess the outcomes while maintaining appropriate documentation and results. MTM programs should be evaluated and revised on a continuing basis to ensure that appropriate quality and continued value is maintained.

**Provider Status for Pharmacists** 

Policy 1201

06/01/2013 Introduced 03/27/2017 Revised 07/19/2018 Revised 10/22/2018 Revised The Academy of Managed Care Pharmacy (AMCP) supports the recognition of pharmacists as providers under the Social Security Act. Pharmacists provide measurable improvements in healthcare outcomes and patientsatisfaction and reduce overall healthcare expenditures. AMCP strongly believes the formal recognition of pharmacists as health care providers will increase their contribution to address primary healthcare needs, including medication administration, as part of collaborative healthcare with fewer barriers.

(See AMCP Where We Stand Position Statement – *Provider Status for Pharmacists*)

### **RESEARCH**

Role of Pharmacists in Outcomes Research

Policy 9927

11/01/1999 Introduced 03/01/2004 Reapproved 12/01/2008 Reapproved 10/01/2012 Reapproved 02/21/2018 Reapproved AMCP supports the role of pharmacists in outcomes research, including those processes by which health care systems identify treatment and/or procedural issues, complete interventions to correct deficiencies, and conduct evaluations to measure results and improve care in defined patient populations. In order to improve the appropriate use of medications, enhance favorable patient outcomes, and improve the cost-effectiveness and cost-efficiency of health care, managed health care systems must implement strategies based on credible, relevant outcomes research. Pharmacists are well positioned to design and implement programs and policies to influence the practice of prescribers and pharmacists and to evaluate the effect of these programs on patient outcomes.

(See AMCP Concepts in Managed Care Pharmacy – *Outcomes Research*).

Clinical Investigations	in
Children	

Policy 0003

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Reapproved 02/01/2014 Revised AMCP supports the inclusion of children in clinical investigations of drug products where appropriate safeguards are instituted to ensure the safety of children; where the use of the drug has significant indications (need for use) in children, and where appropriate, there is prior experience with the drug in the adult population.

Complementary and Alternative Medications

Policy 0004

02/01/2000 Introduced 02/01/2003 Revised 02/01/2008 Reapproved 10/01/2012 Reapproved

Health and Wellness Grants

Policy 0013

02/01/2000 Introduced 02/01/2005 Reapproved 11/01/2009 Revised 02/01/2014 Reapproved AMCP supports the demonstration of safety and efficacy of complementary and alternative medicines, based on well-designed scientific studies. AMCP recognizes the importance of patient autonomy regarding the use of complementary and alternative medicines in making their health care decisions, and health care professionals should help to educate patients who choose to use complementary and alternative medicines.

AMCP supports the establishment of government funding and grants for health care research and implementation of programs including those proposed by pharmacists and pharmaceutical organizations. Investigational Drug Use

Policy 0103

03/01/2001 Introduced 11/01/2005 Revised 11/01/2009 Reapproved AMCP supports the involvement of pharmacists in the management of drugs used in clinical research studies. In addition, AMCP supports pharmacist participation with pharmacy and therapeutics committees and institutional review boards in the design and performance of medication-related clinical research.

Pharmacogenomics

Policy 0107

03/01/2001 Introduced 11/01/2005 Reapproved 11/01/2009 Revised 02/01/2014 Revised 02/21/2018 Reapproved

Regulation of Dietary Supplements

Policy 0110

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Reapproved

Comparative Effectiveness of Prescription Drugs

Policy 0501

02/05/2005 Introduced 11/01/2009 Reapproved 02/01/2014 Revised AMCP supports further research and assessment of the economic, clinical, and humanistic impact of pharmacogenomics on managed care pharmacy practice. AMCP supports the pharmacist's leadership role in the review and evaluation of scientific evidence and the subsequent development of pharmaceutical care processes involving these therapies through collaboration with other health care practitioners and consumer organizations. Pharmacy and Therapeutics Committees in collaboration with Health Technology Assessment committees should be involved in the decision-making process related to coverage of genetic tests and utilization management strategies.

AMCP advocates the modification of the Dietary Supplement Health and Education Act or enactment of other legislation for all products falling under the Act, requiring that dietary supplement manufacturers provide evidence of product efficacy and safety, label products with full disclosure of all components (including source, strength, and recommendations for use), and implement a mechanism to remove promptly unsafe or ineffective products from the marketplace. AMCP encourages expansion of the National Institutes of Health Office of Dietary Supplement's Internet site to include reports of adverse health events from manufacturers, health care professionals, consumers, the Food and Drug Administration, and the Center for Food Safety and Applied Nutrition.

The purpose of comparative effectiveness research is to assist consumers, clinicians, purchasers and policymakers to make informed decisions that will improve health care at both the individual and population levels. Academy supports research and the development of practical tools to provide guidance on the comparative effectiveness and value of prescription drugs to improve patient outcomes. Recent legislation, including the Affordable Care Act, has directed new funding toward this research. The Academy believes that the federal government must continue to assume principal responsibility for sponsoring this type of research. Such research is a fundamentally necessary component of any rational approach to determining the value and usefulness of prescription drugs. Currently, only limited authoritative research exists that distinguishes the effectiveness and safety profile offered by any particular drug as compared to other drugs in the same or a similar treatment class. The Academy believes that patient treatment decisions must take into account the clinical effectiveness and safety of prescription drugs and that a decision to utilize prescription drugs must be based upon the strength of credible scientific evidence and best practices.

(See AMCP Where We Stand Position Statement – *Comparative Effectiveness of Prescription Drugs*)

Integrity in Clinical Trials

Policy 0701

04/01/2007 Introduced 02/21/2018 Reapproved

AMCP supports the Association of American Medical Colleges (AAMC) Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials. The AAMC Principles provide a guide for the ethical and operational facets of data access, analysis, and reporting to assure integrity and credibility in the conduct and reporting of clinical trials.

(See AAMC Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials,

https://www.aamc.org/download/49882/data/clinical trials reporting.pdf)

**Biosimilar Drug Therapies** 

Policy 0802

06/01/2008 Introduced 04/01/2012 Revised 10/01/2012 Reapproved AMCP supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies. In order to strike an appropriate balance between bringing safe and effective drugs to market and maximizing patient access to affordable drugs, the FDA should determine on a case-by-case basis the need for additional clinical studies prior to approval, as well as any post-marketing studies. Manufacturers of approved biosimilars should be allowed to use the same government-approved/international non-proprietary name as the reference product. The FDA should also provide clear rules for the designation of a biosimilar product as interchangeable with a reference product, similar to the current "AB" ratings used for small-molecule chemical drugs. A designation of interchangeability should not be a requirement as a condition for approval of a biosimilar product.

(See AMCP Where We Stand Position Statement – *Biosimilar Drug Therapies*)

# **SPECIALTY PHARMACY/ BIOSIMILARS**

**Generic Drug Products** 

Policy 9911

11/01/1999 Introduced 02/01/2005 Revised 11/01/2009 Revised 02/01/2014 Revised AMCP encourages pharmacists and managed health care systems to promote the use and benefits of FDA-approved and therapeutically equivalent generic drug products as safe, effective, and costeffective alternatives to brand-name equivalents. AMCP supports legislative and regulatory changes that would promote the development and use of safe, efficacious and equivalent generic drugs and eliminate barriers that can unnecessarily delay the entry of the generic drugs into the marketplace. AMCP believes that Congress must ensure that the FDA has access to adequate resources in order to review and process applications for generic drugs and eliminate unnecessary delays of their approval. AMCP opposes state and federal legislative and regulatory provisions that would restrict the right of pharmacists, in collaboration with prescribers and patients, to exercise their professional judgment in choosing the most appropriate generic or brand-name equivalent products for patients.

(See AMCP Where We Stand Position Statement – Generic Drugs)

(See also AMCP Where We Stand Position Statement on *Biosimilar Drug Therapies*)

## **Specialty Pharmaceuticals**

#### Policy 0112

03/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised AMCP encourages pharmacists to take a leadership role in their practice site for proper use and administration of specialty pharmaceuticals, which includes care management, storage, control, safe handling, preparation, administrative procedures, and distribution. Specialty pharmaceuticals are generally high-cost medications, usually prescribed for people with complex or chronic medical conditions, or they may be medications that typically exhibit one or more of the following characteristics:

- drugs that are injected or infused, however, some may be taken by mouth;
- drugs that have unique monitoring, storage or shipment requirements; and
- drugs that require additional education and supports from a health care professional

# Restricted Distribution of Pharmaceuticals

#### Policy 0119

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Revised AMCP generally opposes any restrictions on the distribution of pharmaceutical products either by the pharmaceutical industry or as a condition for FDA-approval. AMCP acknowledges that circumstances may occur with the use of specific medications that require special distribution, monitoring and management processes. As long as,

- 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 physicians, 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 cost 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;
- 7. The requirements do not interfere with the professional practice of pharmacists, physicians, or other appropriately qualified healthcare professionals.

(The enumerated principles are drawn from ASHP *Principles for Restricted Distribution Systems*. June 2007)

#### **Biosimilar Drug Therapies**

Policy 0802

06/01/2008 Introduced 04/01/2012 Revised 10/01/2012 Reapproved AMCP supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies. In order to strike an appropriate balance between bringing safe and effective drugs to market and maximizing patient access to affordable drugs, the FDA should determine on a case-by-case basis the need for additional clinical studies prior to approval, as well as any post-marketing studies. Manufacturers of approved biosimilars should be allowed to use the same government-approved/international non-proprietary name as the reference product. The FDA should also provide clear rules for the designation of a biosimilar product as interchangeable with a reference product, similar to the current "AB" ratings used for small-molecule chemical drugs. A designation of interchangeability should not be a requirement as a condition for approval of a biosimilar product.

(See AMCP Where We Stand Position Statement – *Biosimilar Drug Therapies*)

**Preferred Pharmacy Networks** 

Policy 1401

07/29/14 Introduced

The Academy of Managed Care Pharmacy (AMCP) supports the ability of health plans to offer preferred pharmacy networks for their enrollees as a way of providing additional options and cost savings without any diminishment of quality or patient access. Preferred pharmacy networks represent an important tool and innovation in managed care pharmacy benefits. The Academy supports the continued use of these programs as a beneficial way to maintain quality of care, access and cost effectiveness to the pharmacy benefit.

#### SUPPLY CHAIN MANAGEMENT

**Drug and Device Recalls** 

Policy 0009

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP supports the use of technologies to enhance communication of recall information to all relevant parties including patients who may have received such products.

**Drug Integrity and Stability** 

Policy 0010

02/01/2000 Introduced 02/01/2005 Revised 11/01/2009 Reapproved AMCP encourages all entities involved in the distribution of pharmaceutical products to assure that drug product integrity and stability is maintained throughout the continuum of the drug distribution system.

Restricted Distribution of Pharmaceuticals

Policy 0119

11/01/2001 Introduced 02/01/2006 Revised 12/01/2010 Revised 04/07/2015 Revised AMCP generally opposes any restrictions on the distribution of pharmaceutical products either by the pharmaceutical industry or as a condition for FDA-approval. AMCP acknowledges that circumstances may occur with the use of specific medications that require special distribution, monitoring and management processes. As long as,

- 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 physicians, 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 cost 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;
- 7. The requirements do not interfere with the professional practice of pharmacists, physicians, or other appropriately qualified healthcare professionals.

(The enumerated principles are drawn from ASHP *Principles for Restricted Distribution Systems*. June 2007)

**Prescription Drug Importation** Legislation that would permit the importation of prescription drugs presents potential patient safety issues. Allowing the importation of Policy 0302 prescription drugs raises a challenge to ensure that quality assurance standards have been maintained. AMCP believes that more conclusive data are needed as to the likely impact of 02/01/2003 Introduced 02/01/2008 Revised importation. AMCP will oppose legislation that would allow the 02/01/2013 Revised importation of prescription drugs for sale in the United States until more conclusive data are available as to its likely impact. (See also AMCP Where We Stand Position Statement – Prescription Drug Importation) **Pharmaceutical Counterfeiting** AMCP supports efforts to increase health care professional and public awareness of medication counterfeiting. AMCP supports the Policy 0505 purchase and handling of medications in ways that enhance the transparency and integrity of the drug product supply chain and 10/01/2005 Introduced encourages pharmacists to identify instances of drug product 02/01/2010 Reapproved counterfeiting. AMCP encourages efforts to provide consumers and health care professionals with information on how to avoid counterfeit drug products and how to recognize, respond to, and report encounters with suspicious drug products. AMCP backs efforts to foster research and education on the extent, methods, and impact of drug product counterfeiting and on strategies for preventing and responding to drug product counterfeiting. **Drug Shortages** AMCP encourages health care stakeholders, government agencies, and the pharmaceutical industry to work collaboratively to seek Policy 1102 proactive and strategic solutions to minimize the number and impact of drug shortages on the drug distribution process and

patient outcomes.

10/01/2011 Introduced

# **WORKFORCE**

Pharmacist Census	AMCP supports the ongoing Pharmacy Manpower Project efforts to conduct a periodic census of pharmacists which established a
Policy 0117	baseline and tracks changes in workforce demographics and practice characteristics.
11/01/2001 Introduced	
02/01/2006 Revised	
12/01/2010 Revised	
04/07/2015 Reapproved	