

Principles of a Sound Drug Formulary System

These principles have been endorsed by the following organizations:

- Academy of Managed Care Pharmacy
- Alliance of Community Health Plans
- American Medical Association
- American Society of Health-System Pharmacists
- Department of Veterans Affairs,
Pharmacy Benefits Management
Strategic Healthcare Group
- National Business Coalition on Health
- U. S. Pharmacopeia

October 2000

Principles of a Sound Drug Formulary System

PREAMBLE

A coalition of national organizations representing health care professionals, government, and business leaders formed a working group (See Appendix III) to develop a set of principles specifying the essential components that contribute to a sound drug formulary system. The Coalition was formed in September 1999 in response to the widespread use of drug formularies in both inpatient and outpatient settings and the lack of understanding about formularies among the public. Also, proposed federal legislation that would provide a prescription drug benefit for Medicare beneficiaries has brought increased attention to the appropriate role and management of drug formulary systems within drug benefit programs.

The formulary system, when properly designed and implemented, can promote rational, clinically appropriate, safe, and cost-effective drug therapy. The Coalition has enumerated these principles, however, because it recognizes that patient care may be compromised if a formulary system is not optimally developed, organized and administered. This document contains “Guiding Principles” that the Coalition believes must be present for a drug formulary system to appropriately serve the patients it covers. The absence of one or more of these “Guiding Principles” should be cause for careful scrutiny of a formulary system. A glossary (See Appendix I) and bibliography (See Appendix II) are included with the “Guiding Principles” to clarify terminology and to provide additional resources, respectively.

The Coalition believes that the presence of consensus-based Formulary System Principles can assist decision-makers who must balance the health care quality and cost equation. Further, the Guiding Principles will be a valuable educational tool for national, state and local public policy makers, health care system administrators, purchasers and third party payers, practitioners, and consumers and patient advocates. These parties all have an interest in designing formulary systems that ensure patients have access to rational, clinically appropriate, safe, and cost-effective therapy and which supports an affordable and sustainable drug benefit program.

DEFINITIONS

Drug Formulary System - an ongoing process whereby a health care organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.

Drug Formulary - a continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists and other experts in the diagnosis and/or treatment of disease and promotion of health.

GUIDING PRINCIPLES

Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost effective drug therapy.

The formulary system encompasses drug selection, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, and monitoring of outcomes.

- ❖ Clinical decisions are based on the strength of scientific evidence and standards of practice that include, but are not limited, to the following:
 - ◆ Assessing peer-reviewed medical literature, including: randomized clinical trials (especially drug comparison studies), pharmacoeconomic studies, and outcomes research data.
 - ◆ Employing published practice guidelines, developed by an acceptable evidence-based process.
 - ◆ Comparing the efficacy as well as the type and frequency of side effects and potential drug interactions among alternative drug products.
 - ◆ Assessing the likely impact of a drug product on patient compliance when compared to alternative products.
 - ◆ Basing formulary system decisions on a thorough evaluation of the benefits, risks and potential outcomes for patients; risks encompass adverse drug events (adverse drug reactions and medication errors, such as those caused by confusing product names or labels).

- ❖ Economic considerations include, but are not limited, to the following:
 - ◆ Basing formulary system decisions on cost factors only after the safety, efficacy and therapeutic need have been established.
 - ◆ Evaluating drug products and therapies in terms of their impact on total health care costs.
 - ◆ Permitting financial incentives only when they promote cost management as part of the delivery of quality medical care. Financial incentives or pressures on practitioners that may interfere with the delivery of medically necessary care are unacceptable.

- ❖ The formulary system:
 - ◆ Provides drug product selection and formulary maintenance (see above).
 - ◆ Provides drug use evaluation (also called drug utilization review) to enhance quality of care for patients by assuring appropriate drug therapy.
 - ◆ Provides for the periodic evaluation and analysis of treatment protocols and procedures to ensure that they are up-to-date and are consistent with optimum therapeutics.
 - ◆ Provides for the monitoring, reporting, and analysis of adverse results of drug therapy (e.g., adverse drug reactions, medication errors) to continuously improve the quality of care.

GUIDING PRINCIPLES

The Pharmacy and Therapeutics (P&T) Committee, or equivalent body, comprised of actively practicing physicians, pharmacists and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products.

Physicians, pharmacists, and other health care professionals provide oversight of the formulary system.

The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members.

- ❖ The Pharmacy and Therapeutics Committee:
 - ◆ Objectively appraises, evaluates, and selects drugs for the formulary.
 - ◆ Meets as frequently as is necessary to review and update the appropriateness of the formulary system in light of new drugs and new indications, uses, or warnings affecting existing drugs.
 - ◆ Establishes policies and procedures to educate and inform health care providers about drug products, usage, and committee decisions.
 - ◆ Oversees quality improvement programs that employ drug use evaluation.
 - ◆ Implements generic substitution and therapeutic interchange programs that authorize exchange of therapeutic alternatives based upon written guidelines or protocols within a formulary system. (Note: Therapeutic substitution, the dispensing of therapeutic alternates without the prescriber's approval, is illegal and should not be allowed-See Glossary.)
 - ◆ Develops protocols and procedures for the use of and access to non-formulary drug products.

- ◆ Health care organization policies should ensure appropriate oversight of the P&T Committee and its decisions by the medical staff or equivalent body.

- ❖ Formulary system policies should:
 - ◆ Require P&T committee members to reveal, by signing a conflict of interest statement, economic and other relationships with pharmaceutical entities that could influence Committee decisions.
 - ◆ Exclude product sponsor representatives from P&T committee membership and from attending P & T committee meetings.
 - ◆ Require P&T committee members to adhere to the formulary system's policy on disclosure and participation in discussion as it relates to conflict of interest.

GUIDING PRINCIPLES

The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.

The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.

- ❖ The formulary system should:
 - ◆ Inform physicians, pharmacists, other health care professionals, patients, and payers about the factors that affect formulary system decisions, including: cost containment measures; the procedures for obtaining non-formulary drugs; and the importance of formulary compliance to improving quality of care and restraining health care costs.
 - ◆ Proactively inform practitioners about changes to the formulary or to other pharmaceutical management procedures.
 - ◆ Provide patient education programs that explain how formulary decisions are made and the roles and responsibilities of the patient, especially the importance of patient compliance with drug therapy to assure the success of that therapy.
 - ◆ Disclose the existence of formularies and have copies of the formulary readily available and accessible.
 - ◆ Provide rationale for specific formulary decisions when requested.

- ❖ The formulary system should:
 - ◆ Enable individual patient needs to be met with non-formulary drug products when demonstrated to be clinically justified by the physician or other prescriber.
 - ◆ Institute an efficient process for the timely procurement of non-formulary drug products and impose minimal administrative burdens.
 - ◆ Provide access to a formal appeal process if a request for a non-formulary drug is denied.
 - ◆ Include policies that state that practitioners should not be penalized for prescribing non-formulary drug products that are medically necessary.

APPENDIX I
GLOSSARY

Drug Formulary System - an ongoing process whereby a health care organization, through its physicians, pharmacists and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost effective to best serve the health interests of a given patient population.

Drug Formulary - a continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Pharmacy & Therapeutics (P&T) Committee - an advisory committee that is responsible for developing, managing, updating, and administering the drug formulary system.

Generic Substitution - the substitution of drug products that contain the same active ingredient(s) and are chemically identical in strength, concentration, dosage form, and route of administration to the drug product prescribed.

Therapeutic Alternates - drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses.

Therapeutic Interchange - authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system.

Therapeutic Substitution - the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber. This is an illegal act because only the prescriber may authorize an exchange of therapeutic alternates.

Drug Utilization Review (Drug Use Review, DUR, and Drug Use Evaluation) - process used to assess the appropriateness of drug therapy by engaging in the evaluation of data on drug use in a given health care environment against predetermined criteria and standards.

APPENDIX II

BIBLIOGRAPHY

1. Academy of Managed Care Pharmacy, Concepts in Managed Care Pharmacy Series - Formulary Management (Alexandria, VA: 1998).
2. American Medical Association. Board of Trustees Report PPP, Principles of Drug Utilization Review. In, American Medical Association House of Delegates Proceedings, 140th Annual Meeting. Chicago: American Medical Association; June 1991; 225-227.
3. American Medical Association. Board of Trustees Report 45, Drug Formularies and Therapeutic Interchange. In, American Medical Association House of Delegates Proceedings, 47th Interim Meeting. New Orleans: American Medical Association; December 1993; 155-158.
4. American Medical Association. Council on Ethical and Judicial Affairs Report 2, Managed Care Cost Containment Involving Prescription Drugs. In, American Medical Association House of Delegates Proceedings, 144th Annual Meeting. Chicago: American Medical Association; June 1995; 207-213.
5. American Medical Association. Board of Trustees Report 9, Pharmaceutical Benefits Management Companies. In, American Medical Association House of Delegates Proceedings, 51st Interim Meeting. Dallas: American Medical Association; December 1997; 33-44.
6. American Society of Consultant Pharmacists. Guidelines for the Development of Formulary Systems in Nursing Facilities; July 1996.
7. American Society of Hospital Pharmacists. ASHP Statement on the Formulary System. *Am J Hosp Pharm.* 1983; 40:1384-5.
8. American Society of Hospital Pharmacists. ASHP Guidelines on Formulary System Management. *Am J Hosp Pharm.* 1992; 49:648-52.
9. American Society of Hospital Pharmacists. ASHP Statement on the Pharmacy and Therapeutics Committee. *Am J Hosp Pharm.* 1992; 49:2008-9.
10. American Society of Health-System Pharmacists. ASHP Guidelines on Medication-Use Evaluation. *Am J Health-Syst Pharm.* 1996; 53:1953-5.
11. American Society of Hospital Pharmacists. ASHP Technical Assistance Bulletin on Drug Formularies. *Am J Hosp Pharm.* 1991; 48:791-3.
12. American Society of Hospital Pharmacists. ASHP Technical Assistance Bulletin on the Evaluation of Drugs for Formularies. *Am J Hosp Pharm.* 1988; 45:386-7.
13. Covington TR and Thornton JL. The formulary system: A cornerstone of drug benefit management, in *A Pharmacist's Guide to Principles and Practices of Managed Care Pharmacy.* Ito S and Blackburn S. eds. Foundation for Managed Care Pharmacy, Alexandria VA. 1995: 35-49.
14. Dillon MJ. Drug Formulary Management, in *Managed Care Pharmacy Practice.* Navarro RP ed. Aspen Publishers, Inc., Gaithersburg, MD. 1999: 145-165.
15. Hejna CS and Shepherd MD. Pharmacy and therapeutics committee and formulary development, in *A Pharmacist's Guide to Principles and Practices of Managed Care Pharmacy.* Ito S and Blackburn S. eds. Foundation for Managed Care Pharmacy, Alexandria VA. 1995: 27-34.
16. National Committee for Quality Assurance. UM 10 procedures for pharmaceutical management. 2000 Standards for Accreditation of MCOs. 1999: 58-60.
17. National Committee for Quality Assurance. UM 10 procedures for pharmaceutical management. 2000 Surveyor Guidelines for the Accreditation of MCOs. 1999: 173-182.
18. PCMA Response to American Medical Association Report, I-97, "Pharmaceutical Benefits Management Companies." September 1998.
19. Rucker TD and Schiff GD, Drug formularies: myths-in-formation. *Medical Care* 1990; 28:928-942. Reprinted in *Hospital Pharmacy* 1991; 26:507-514.

APPENDIX III**COALITION
WORKING GROUP****Academy of Managed
Care Pharmacy**

Judith A. Cahill, C.E.B.S.
Executive Director

Richard Fry
Senior Director, Pharmacy Affairs

American Medical Association

Joseph W. Cranston, Ph.D.
Director-Science, Research and
Technology

**American Society of Health-System
Pharmacists**

William A. Zellmer, M.P.H.
Deputy Executive Vice President

Department of Veterans Affairs

John E. Ogden
Director, Pharmacy Services

Michael A. Valentino
Associate Chief Consultant
for Pharmacy Benefits Management

**National Business Coalition
on Health**

Catherine Kunkle
Vice President

U.S. Pharmacopeia

Jacqueline L. Eng
Senior Vice President, Program
Development

Keith W. Johnson
Vice President and Director
New and Off-Label Uses

Thomas R. Fulda
Program Director, Drug Utilization
Review Programs

Nancy B. Mabie
Assistant Director, Pharmacy Affairs

Observer

AARP
David Gross
Senior Policy Advisor
Public Policy Institute

Public Comment Requested

To ensure that knowledgeable and interested parties beyond the Coalition Working Group had an opportunity to contribute to the Principles development process, a preliminary set of principles was distributed for public comment to 50-plus organizations in February 2000. Comments received were thoroughly reviewed and considered by the Coalition Working Group.