Report of the Task Force on Model Guidelines for Formulary Development

Members Present:
William T. Winsley (OH) Chair; Edith G. Goodmaster (CT); Stephen R. Statz (SD); Anthony W. Alexander, Jr. (NJ); Davis C. Hook (SC); and Carl O. Benson (MN).

Others Present:
Donna M. Horn, Executive Committee Liaison; Carmen Catizone, NABP Executive Director/Secretary; Janice Teplitz, NABP staff.

Technical Consultants:
Judith Cahill, Academy of Managed Care Pharmacy; Cynthia Kirman, National Managed Pharmacy Programs Healthcare Initiatives, General Motors Corp; and Pat Donoho, Pharmaceutical Care Management Association.

Introduction:
The Task Force on Model Guidelines for Formulary Development met December 14 and 15, 2000, at the Marriott Suites Hotel in Rosemont, Ill. The Task Force on Model Guidelines for Formulary Development was established by the NABP Executive Committee as the result of a recommendation made by the 1999-2000 Task Force on Licensing of Pharmacy Benefit Managers. Through their deliberations, this Task Force determined that it was not necessary to recommend that individuals whose responsibilities lay solely in the development of formularies or plan options offered to or by health plans be licensed or directly regulated by state boards of pharmacy. They were concerned, however, about the lack of oversight and standards in the area of formulary development and the reliance on marketplace and self-regulatory mechanisms for the protection of the public’s interests. It was the belief of the Task Force members that the state boards of pharmacy could provide some oversight through the recognition of Guidelines for the development, administration, and review of formularies. Therefore, the Task Force on Model Guidelines on Licensing of Pharmacy Benefit Managers recommended that NABP develop or recognize existing model guidelines for the development, management, and review of formularies for health plans.

Review of the Task Force Charge:

1. Review existing guidelines or regulations governing the development, management, and review of formularies for health plans in the following areas:
   1. Appropriate competence and licensure of the pharmacist and practitioners involved in the development, management, and review;
   2. Use of appropriate standards of practice that focus on providing the most optimal care for the patient and include provisions for individual patient differences to be addressed;
3. Disclosure provisions that alert the pharmacist, prescriber, and patient of restrictions or substitutions and detail the reasons and benefits to the affected parties;
4. Quality assurance provisions that examine such areas as patient outcome data, peer review, and the updating and revision of formularies and plan options; and
5. Provisions that address other issues, including but not limited to processes for securing formulary exceptions; emergency provisions that operate outside the formulary; and informed consent for participation and release of information.

Discussion:

The members of the Task Force on Model Guidelines for Formulary Development welcomed invited guests Judith Cahill, executive director, Academy of Managed Care Pharmacy (AMCP) and Patrick Donoho, vice president, Government Affairs and Public Policy, Pharmaceutical Care Management Association (PCMA). Also participating in the dialogue was Cynthia Kirman, manager, National Managed Pharmacy Programs Healthcare Initiatives, General Motors Corp., who teleconferenced with the group.

Cahill focused her remarks on “The Principles of a Sound Drug Formulary System,” (See Attachment on Page 17) a document that was developed by a coalition composed of AMCP, the American Association of Retired Persons, the Alliance of Community Health Plans, the American Medical Association, the American Society of Health-System Pharmacists, the Department of Veteran’s Affairs, the National Business Coalition of Health, and the US Pharmacopeia, Inc.

Cahill discussed the principle components and essential elements of a good formulary system. She noted that the coalition document was initiated for two reasons: the increasing emphasis by public policy makers on the use of formulary management systems as a method of providing necessary access to pharmaceuticals in a cost-effective manner; and the recognition that, while there are several existing guides to formularies for health care professionals, there does not exist a layperson’s explanation of what constitutes a sound drug formulary system. Cahill discussed with Task Force members the following seven guiding principles that form the basis for the coalition statement:

1. Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe, and cost-effective drug therapy.
2. The formulary system encompasses drug selection, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, and monitoring of outcomes.
3. 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.

1 See document titled “Attachment_TFMGFD_Page17”
4. Physicians, pharmacists, and other health care professionals provide oversight of the formulary system.

5. 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.

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

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

Cahill stressed the collaborative nature of the P&T Committee’s decision-making responsibilities and that the role of the pharmacist may vary from organization to organization. Regardless of the extent of the pharmacist’s involvement, however, she pointed out that, as regards the state boards of pharmacy, there is not the instance of individual responsibility and specific patient accountability that is present in the case of dispensing or counseling. Other characteristics that distinguish the formulary system management process from other aspects of pharmacy practice are the therapeutic versus coverage decisions that must be made. The contract provisions of the patient’s health care plan, Cahill noted, govern coverage decisions.

Patrick Donoho provided Task Force members with an overview of the pharmaceutical benefits market as it exists at present and offered a glimpse of future state initiatives in this area. He noted, for example, that in 2001, 39 states would look at formularies. Health plan liability is under consideration in 37 states, and 37 states will consider health plan report cards. Donoho told the Task Force that the increasing cost of benefits, fueled by the aging population, a growing utilization of drugs, and increased third-party coverage, are driving changes in benefit design as providers seek option to hold the line on costs. The result is increased regulatory involvement. As formularies are considered a component of plan design, the states are beginning to consider their regulation. Regulations are already under consideration in three states, Donoho acknowledged, and 36 other states are considering regulatory action in the coming year.

Donoho discussed PCMA’s recently adopted Pharmacy Benefit Management standards and the National Council on Quality Assurance (NCQA) criteria, both of which are voluntary efforts to address the situation. Donoho indicated general support for “Principles of a Sound Drug Formulary System” and termed them a good approach to the formulary development issue.

Cynthia Kirmen brought the employer’s perspective to the discussion. She noted that General Motors spends more on pharmaceuticals than it does on steel for its manufacturing process. Kirmen reviewed GM’s benefit package and the dilemma facing the company. She noted that GM and other providers will have to drastically change the way they administer their health care plans unless something is done to control costs. Kirman was supportive of the coalition document, deeming it well done and clinically sound.

Following the presentations of the invited guests, Task Force members began to address their charge.

**TFMGFD Recommendation #1**
The Task Force on Model Guidelines for Formulary Development recommends that, as part of their responsibilities for licensing Pharmacy Benefit Managers (PBMs), state boards of pharmacy include the review of drug formularies as a component of licensure in order to ensure that decisions are being made in the best interest of patients and in accordance with NABP’s principles of outcomes regulation.

**Background:**

Task Force members agreed that the development and use of drug formularies is a national issue that will assume even greater importance should Congress decide to add a prescription drug benefit to the Medicare program. NABP’s 1999-2000 Task Force on Model Guidelines on Licensing of Pharmacy Benefit Managers recommended the incorporation of language in the Model State Pharmacy Act that would specifically recognize PBMs engaged in the practice of pharmacy as entities that must be licensed by the state boards of pharmacy. They agreed that the inclusion of these entities in the licensing section would alert states to the importance of requiring the licensure of PBMs and provide the statutory basis for states to regulate their pharmacy practice activities.

Since the NABP Executive Committee accepted this recommendation, members of the Task Force on Model Guidelines for Formulary Development believe it is appropriate that boards of pharmacy, in their outcomes approach to regulation, include provisions that require the PBM to review the formulary systems utilized by PBMs seeking state licensure.

**TFMGFD Recommendation #2**

The Task Force on Model Guidelines for Formulary Development recommends that when developing drug formularies, Pharmacy Benefit Managers use as one guide a reference, such as “Principles of a Sound Drug Formulary,” which has been endorsed by a coalition of seven pharmacy and health care-related organizations, but also adding the following additional underlined considerations to the Coalition’s original Guiding Principles:

**Guiding Principle:** 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.

♦ Exclude product sponsor representatives from P&T committee membership and from attending P&T committee meetings unless their expert participation is invited.

**Guiding Principle:** The formulary system should include educational programs for payers, practitioners, and patient concerning their roles and responsibilities.

♦ Provide and actively promote 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 ensure the success of that therapy.

♦ Disclose the existence of formularies to patients and have copies of the formulary readily available and accessible.
♦ To ensure dissemination of information, any quality-related event discovered during adverse result surveillance activities should be reported to the appropriate organization or agency, such as the FDA’s MedWatch program.

Guiding Principle: The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.
♦ Institute an efficient process for the timely procurement of non-formulary drug products and impose minimal administrative burdens, including immediate access to clinical decision-makers.
♦ Provide access to a prompt, formal appeal process if a request for a non-formulary drug is denied.

Background:

Task Force members voiced support for “Principles of a Sound Drug Formulary” as one of the references to be utilized by PBMs but identified several areas they felt could be strengthened to further protect and educate patients.

Regarding the fifth Guiding Principle, which states, “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,” they agreed that, in most instances, conflict of interest concerns would preclude representatives of product sponsors from participating in P&T Committee discussions in most instances. They also noted, however, that in certain situations such as in the case of a biomedical drug product, the product representative may be the only “expert” available to discuss the value of the drug with the Committee. As a result, the Task Force recommended the addition of language that would permit sponsor representation if invited by the P&T Committee.

Task Force members were particularly concerned with the sixth Guiding Principle, “The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.” They strongly agreed that the education component is one of the most important compelling principles of the guideline document. They fortified the language supporting the principle to require the active promotion of patient education programs that would take the extra step of reaching out to the public, rather than waiting for the patient to discover the existence of the formulary. Task Force members were united in their belief that formularies should be easily accessible to patients. They stated that it is a health plan’s obligation to explain to its members in user-friendly terms why the formulary is in place, what changes have taken place, and how they can get answers to their questions. They noted that the Internet and point of care devices could lessen the need to provide the more expensive and weighty printed documents.

Of further concern to the Task Force was the need to identify and report quality-related events to the proper tracking organization. In line with NABP’s regulating for pharmaceutical care outcomes project, the Task Force urged that formulary development systems consider the advisability of reporting quality-related events identified during adverse result surveillance activities to such recognized tracking organizations as FDA’s MedWatch program.
Task Force members agreed with the concept of the seventh principle, “The formulary system should indicate a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.” While they supported the need for “the timely procurement of non-formulary drug products” and “minimal administrative burdens,” they also believed that it was critical for the health care professional to be able to immediately access the appropriate decision-maker in a situation where a non-formulary drug is needed. This rapid response, in addition to a prompt appeal process would, they felt, further the goal of better patient outcomes.

**TFMGFD Recommendation #3**

The Task Force on Model Guidelines for Formulary Development urges the NABP Executive Committee that, should a prescription drug program be added to the Medicare program, NABP should work with other groups as appropriate to establish principles of formulary development that may be endorsed on the national level.

**Background:**

Task Force members discussed the likelihood of a prescription drug benefit being added to the federal Medicare program in the near future. Should the prescription drug benefit become a reality, they noted it would be necessary to develop a federal drug formulary system to serve the program. As the national organization representing the state boards of pharmacy, Task Force members agreed that NABP would be a stakeholder in such an undertaking and should participate in any effort to develop a Medicare drug formulary system.

**TFMGFD Recommendation #4**

The Task Force on Model Guidelines for Formulary Development encourages the coalition of organizations endorsing the “Principles of a Sound Drug Formulary” to actively promote and disseminate the document to national and state health care organizations; appropriate federal agencies; actively practicing physicians, pharmacists, and other health care practitioners; and public interest and protection groups.

**Background:**

The Task Force found “Principles of a Sound Drug Formulary” to be an effective and useful guide to those organizations developing drug formularies. They were particularly supportive of the education principles targeting health care professionals and patients but noted that, unless the document was actively promoted and unless activities were initiated to purposely reach out to affected practitioners, patients, and caregivers, its full potential would go unfulfilled. The coalition of organizations endorsing the document is urged to publicly and actively endorse its value and make it available to all stakeholders and the organizations that represent them.
Principles of a Sound Drug Formulary System

October 2000

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

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 the “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 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 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 judgment 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), pharmaco-economic 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 pressure 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, 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 warning 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.

❖ 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 judgment 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 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

Appendix III
Coalition Working Group

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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.