Health Services
LOS ANGELES COUNTY

POLICIES AND PROCEDURES

SUBJECT: DHS CORE PHARMACY AND THERAPEUTICS (P&T) FORMULARY SELECTION AND MAINTENANCE PROCESS

POLICY NO: 329.002

PURPOSE:

This policy outlines the formulary selection process utilized by the Department of Health Services (DHS) Core Pharmacy and Therapeutics (P&T) Committee. The governing principle of this process is the promotion of a rational, clinically appropriate, safe, and cost-effective uniform drug formulary for use by all DHS facilities and community partners. The DHS Core Formulary process focuses on the availability of necessary pharmaceutical agents to appropriately serve our patient population as well as the support of an affordable and sustainable drug benefit program for DHS patients.

This policy thoroughly outlines steps involved in the formulary selection process and highlights appropriate measures taken to ensure the integrity of this process.

POLICY:

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

I. Clinical decisions are based on the strength of scientific evidence and standards of practice that include, but are not limited to the following:

   A. Assessing peer-reviewed medical literature, including randomized clinical trials (particularly drug comparison studies), pharmacoeconomic studies, and outcome research data.

   B. Employing published practice guidelines, developed by an acceptable evidence-based review process.

   C. Comparing the efficacy as well as type and frequency of side effects and potential drug interactions among alternative drug products.

   D. Assessing the likely impact of a drug product on patient compliance when compared to alternative products.

E. Basing formulary system decisions on a thorough analysis of the benefits, risks, and potential outcomes of patients; risks encompass adverse drug events (adverse drug reactions and preventable medication errors, such as those that may be caused by confusing product names or labels).

F. Utilize outside reference sources (e.g. Institute for Safe Medication Practices, FDA MedWatch, FDA black box warnings) for review against the Core Drug Formulary, in an effort to promote the safe use of medications.

II. Economic considerations include, but are not limited to the following:

A. Basing formulary system decisions on cost factors after the safety, efficacy and therapeutic need has been established.

B. Evaluating drug products and therapies in terms of their impact on total health system costs, as the pharmaceutical manufacturer offers different drug costs (per health care setting) for the same therapeutic agent.

C. Permitting financial incentives only when they promote cost management as part of the delivery of quality health care.

DEFINITION:

***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 health promotion.

PROCEDURE:

I. Requests for drugs additions, deletions, or restriction changes to the DHS Core Formulary are initiated at the DHS Facility P&T Committee level and forwarded as recommendations to the DHS Core P&T Committee. In addition, the DHS Chief Pharmacy Officer, DHS Chief Medical Officer (or designee), or a DHS Core P&T Committee expert panel may forward formulary recommendations to the DHS Core P&T Committee.

A. The DHS Chief Pharmacy Officer will automatically delete, from the DHS Core Formulary, pharmacologic agents that are no longer available from the manufacturer. Notification of these deletions shall be presented to the DHS Core

P&T Committee for informational purposes, as well as to assess the formulary availability of alternate products.

II. A drug review may be initiated in the following ways:

A. A request for formulary consideration may be initiated by an attending physician or pharmacist. The DHS Facility P&T Committee reviews formulary request forms, and provides a preliminary recommendation to accept or reject. If accepted at the facility level, the DHS Facility P&T Committee may recommend guidelines and/or restrictions for the use of the product. The accepted DHS Facility P&T Committee recommendation is then forwarded to the DHS Chief Pharmacy Officer for review by the DHS Core P&T Committee.

B. A request for formulary consideration may be forwarded by either the DHS Chief Pharmacy Officer or DHS Chief Medical Officer (or designee), typically due to changes in manufacturer availability of specific products or as a result of a preferred contract negotiated by DHS Pharmacy.

C. An authorized expert panel of the DHS Core P&T Committee may recommend formulary changes for review. All expert panel recommendations submitted for DHS Core P&T Committee review shall be accompanied by a written summary of the expert panel meeting discussion, participant list, final vote, recommendations, and reference sources.

III. Requirements for DHS Facility P&T Committee formulary submissions:

A. Original signed formulary request form listing justification for formulary change.

B. Conflict of Interest (COI) form completed and signed by the requestor.

C. Relevant supporting peer reviewed medical literature.

IV. DHS Pharmacy further evaluates each request, reviews pertinent information as described in Policy (I) above, and assesses economic impact as described in Policy (II) above. The minimum time from which a drug request is received and presented to the DHS Core P&T Committee meeting is 4 weeks, unless a review is designated as urgent by the DHS Facility P&T Committee. Certain drug requests may be deferred for a pending therapeutic class review or expert panel review as appropriate.

V. The DHS Core P&T Committee provides final decisions regarding changes to the DHS Core Formulary. The DHS Core P&T Committee decision is final, but subject to review if relevant new information is available that warrants reconsideration. If a formulary request is rejected, a formulary request for the same agent will not be considered again for 12 months unless important relevant peer reviewed medical literature is provided that supports reconsideration of the formulary decision.

VI. The DHS Core P&T Committee may establish expert panels for consideration of formulary requests and reviews for specialty agents. The expert panel will include participation from the majority, if not all, the facilities expected to utilize the particular agent. Expert panel recommendations will be forwarded to the DHS Core P&T Committee for final decision.

VII. The DHS Core P&T Committee will conduct regular therapeutic class reviews, in an effort to ensure that the DHS Core Formulary is updated on a regular basis and reflects current medically accepted practice standards. DHS Facility P&T Committees may forward requests for therapeutic class reviews to the DHS Core P&T Committee for consideration.

REFERENCES:

Principles of a Sound Drug Formulary System: American Society of Health Systems Pharmacists, June 2000. Principles endorsed by:

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