CHAPTER 19

THE FORMULARY SYSTEM
Formulary System
In the Nursing Home

I. OTC Formulary for Medicaid Residents (Patient Care Formulary)

1. OTC medications must be available for Medicaid residents.
2. The facility must maintain a formulary of OTC meds in selected therapeutic categories as part of their daily reimbursement from Medicaid.
3. Must be provided free of charge to Medicaid residents (with a valid doctor’s order).
4. If a brand name product is desired by the resident (other than the one selected by the nursing home) the facility may charge the resident UNLESS the MD writes specifically for the branded product.
5. Monitoring
6. Storage
7. Sizes to stock
8. Labeling
9. Should have more than one of each category

II. P.P.S. Managed Care Formulary

Some facilities maintain a formulary for their Medicare and Managed Care patients to help control drug costs for the facility. These formularies are “open” formularies which means that a prescriber may elect to write for a medication not covered in the formulary. The facility is obligated to obtain the medication even though the drug is not part of the formulary. These formularies are frequently seen when the facility pays their vendor pharmacy a capitated or “per diem” rate for the patients medications.

III. Brand Interchange

1. Policy regarding interchanges.
   A. Board of Pharmacy statement regarding interchanges
   B. Negative formulary
2. Therapeutic substitution or equivalent

IV. Medicare Part D Formularies

Each Medicare PDP will have their own formulary. It is likely that the vendor Pharmacy and the Consultant Pharmacist will be required to manage multiple formularies depending on the number of PDP’s represented in the facility.
THIS IS A FORMER REGULATION THAT SPELLED OUT THE MINIMUM OTC FLOOR STOCK LIST

FLORIDA ADMINISTRATIVE CODE

RULE 59G-4.200

NURSING HOME SERVICES

59G-4.200 Nursing Home Services.

(a) The Medicaid payment is an all-inclusive payment designed to reimburse an efficiently and economically operated nursing home for costs incurred in providing daily nursing care to Medicaid recipients.

(b) Items of necessary expense incurred by the nursing home provider in providing resident care shall be included as allowable costs in the nursing home's cost report and shall not be charged to the recipient. These allowable costs are defined as items of expense that the provider is required to incur in furnishing skilled and intermediate care services or any expenses incurred that are necessary to comply with State licensure and Federal certification requirements. The nursing home shall stock the routine and ancillary items described below, maintain a listing of all stock items, make such listing available to residents and their responsible parties upon admission to the nursing home, and when determined medically necessary by the resident's physician as documented in the resident's medical record, shall supply these items at no cost to the resident. If the resident refuses to use the stock brand of an item, and demands an alternate brand, the nursing home shall document the demand in the resident's medical record and the resident shall be responsible for the cost of the item. If the physician orders liquid versus the stockd solid form or if the situation is reversed, the item shall still be the responsibility of the facility and not charged to the resident.

(c) The Medicaid payment includes, but is not limited to, reimbursement for the following items:

1. Room and board including all of the items necessary to furnish a resident's room;
2. Dietary, rehabilitative and nursing services including the professional handling and personal care of the resident;
3. Medical supplies provided for a resident when medically necessary, including:
   a. Catheters, catheter irrigation trays, and related supplies.
   b. Bandages, adhesive strips, dressings and sterile gauze.
   c. Linen savers, diapers, waterproof pads, rubber pants, and sanitary napkins.
   d. Needles and syringes.
   e. Air mattresses, neoprene plastic pads, bed pads, bed protectors, and sheetpads.

f. Laxatives — at least one product of each of the following categories:
   (i) Bulk.
   (ii) Pectin powder.
   (iii) Ipecac.
   (iv) Saline.
   (v) Emollient.
   (vi) Enema.

(g) Non-legend analgesics — at least one product of each of the following categories:
   (i) Aspirin.
   (ii) Acetaminophen, and
   (iii) Ibuprofen.

(h) Non-legend antacid — at least one product of each of the following categories:
   (i) Magnesium hydroxide and aluminum hydroxide with or without Simethicone.
   (ii) Aluminum hydroxide.

(i) Non-legend vitamin — at least one product of each of the following categories:
   (i) Oil and water soluble multiple vitamins without minerals.
   (ii) Oil and water soluble multiple vitamins with minerals.
   (iii) Ferrous sulfate, ferrous gluconate and ferrous fumarate products.
   (iv) Therapeutic multivitamin mineral combination.
   (v) B-Complex with vitamin C, stress formula.

(j) Dietary supplements, salt and sugar substitutes, and tube feedings.

(k) Medicinal alcohol, hydrogen peroxide, antiseptics, tincture of benzoin, bulk epsom salts for soaking, and providone-iodine ointment and solution.

(l) Cotton balls, tissue, applicators, body oil or body lotion, powder, lemon glycine swabs, and cotton swabs.

(m) Colostomy bags and related supplies and ileostomy supplies.

(n) Non-legend cough preparations — at least one product of each of the following categories:
   (i) Expectorant
   (ii) Combination of expectorant and cough suppressant.

   o. Blood glucose strips.
   q. Bland ointment.
   r. Ophthalmic lubricant.
   s. Oxygen and the equipment and supplies needed to dispense the oxygen.
   t. First aid supplies.
   v. Moisturizing spray and ointment for treatment of pressure sores.

59G-4.200—MEDICAID RULE 59G-4 P.A.C.

Revised February 1993
CURRENT GUIDANCE REGARDING OTC FLOOR STOCK
IN A NURSING HOME

Except for the drugs specified under the topic, “Covered Services, Non-legend Drugs and Supplies,” in this chapter, over-the-counter (non-legend) drugs are not covered. For institutionalized recipients, all over-the-counter drugs, supplies, food supplements, and vitamins are considered nursing home floor stock and are reimbursed in the long-term care provider’s per diem rate.
NURSING HOME

SAMPLE POLICY & METHODS
Non-Prescription Floor Stock

POLICY:
It is the policy of this facility to maintain a stock of non-prescription drugs for the routine use of the residents on the written orders of the physician.

METHODS:
1. The following drugs will be furnished to the resident on the written order of the physician for the routine use and without charge to the resident:

Laxatives:
   1. Bulk - natural vegetable powder - same as Metamucil
   2. Fecal softener - dioctyl sodium succinate - same as Colace
   3. Irritant - danthron - same as Modane
   4. Biscodyl suppositories - same as Dulcolax
   5. Saline - milk of magnesia - same as MOM
   6. Emolient - mineral oil - same as MO
   7. Enema - saline enema - same as Fleets Enema

Analgesics:
   1. Aspirin - tablets and suppositories - same as ASA
   2. Acetaminophen - tablets, liquids, suppositories - same as Tylenol

Antacids:
   1. Magnesium hydroxide - same as Maalox
   2. Aluminum hydroxide gel - same as Amphogel

Multiple Vitamins:
   1. Multiple vitamins liquid and tablets - same as Theragran
   2. Multiple vitamins with minerals - same as Theragran M
   3. Vitamin B complex - same as Allbee C capsules or generic equivalent

Diarrhea:
   1. Kaopectate or generic equivalent
NURSING HOME

SAMPLE POLICY & METHODS

Hematinic:
1. Ferrous gluconate - same as Fergon

Cough Syrups:
1. Expectorant - same as Robitussin
2. Expectorant with suppressant - same as Robitussin DM

Bland Ointment:
1. Petroleum jelly - same as vaseline

Ophthalmic Lubricant:
1. Artificial tears - same as Liquifilm Tears

Topical Antibiotic:
1. Triple antibiotic ointment - same as Neosporin Ointment

In addition to the above, the following will also be made available at no charge to the resident:

(1) An astringent
(2) Tincture benzoin
(3) Bulk Epsom salts for soaking
(4) Body oil
(5) Body lotion
(6) Body powder
(7) Clinitest and Acetest tablets
(8) An iodine scrub and solution - same as Betadine

2. Special brands other than those stocked in the facility if ordered by the family or the physician shall be supplied and billed to the responsible family member.

3. All non-prescription stock medication shall be supplied to the facility in the manufacturer’s original properly labeled containers.

4. The facility reserves the right to select an appropriate brand which may change from time to time.
HOSPITAL

THE FORMULARY SYSTEM

Important component of the medication use process in a hospital.

- **GOAL:** promote rational, appropriate, safe use of drugs
- **GOAL:** Effective way to control drug expenses

Formulary is a continuously updated list of medications (includes strength and dosage form) and related information representing the clinical judgment of the organization that is approved by the medical staff (e.g. Pharmacy and Therapeutics Committee).

The Joint Commission Standard MM.02.01.01.

EP1 Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients.

**EP2 The hospital develops and approves criteria for selecting medications, which, at a minimum, include the following: indications for use, effectiveness, drug interactions, potential for errors and abuse, adverse drug events, sentinel event advisories, population(s) served (for example, pediatrics, geriatrics), other risks, costs.**

EP3 Before using a medication new to the hospital, the hospital determines a method to monitor the response of the patient.

EP4 The hospital maintains a formulary, including medication strength and dosage.

EP5 The hospital makes its formulary readily available to those involved in medication management.

EP6 The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.

EP7 The hospital has a process to select, approve, and procure medications that are not on its formulary.

EP8 The hospital implements the process to select, approve, and procure medications that are not on its formulary.

EP9 Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.

EP10 The hospital has a process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.

EP11 The hospital implements its process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.

EP12 The hospital develops and approves written medication substitution protocols to be used in the event of a medication shortage or outage.

EP13 The hospital implements its approved medication substitution protocols.

EP14 The hospital has a process to communicate to licensed independent practitioners and staff who participate in medication management about the medication substitution protocols for shortages or outages.

EP15 The hospital implements its process to communicate to licensed independent practitioners and staff who participate in medication management about the medication substitution protocols for shortages and outages.
Florida Statutes 465.019 (6)

Class II institutional pharmacy may adopt a formulary system with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by pharmacists employed in the institution. Establish policies and procedures for the development of the formulary system in accordance with American Hospital Association and ASHP standards.

CMS Conditions of Participation §482.25(b)(9)

A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

Formulary Categories

- Formulary
- Formulary Restricted
- Non-Formulary
- Non-Formulary/Not-Available
DEPARTMENT OF PHARMACY SERVICES

POLICY NUMBER: 99-10
CATEGORY: PHARMACY & THERAPEUTICS COMMITTEE

EFFECTIVE DATE: 05/20/1987
DATE REVISED: 05/01/2015
DATE REVIEWED 05/01/2015

TITLE: THE HOSPITAL MEDICATION FORMULARY

POLICY: The Formulary is a list of medications that reflects the clinical judgment of the medical staff and other experts in the diagnosis, prophylaxis, or treatment of disease as well as promotion of health. The Formulary is the nucleus of what is known as the formulary system. This system is a method whereby the medical staff of the hospital, working through the Pharmacy and Therapeutics (P&T) Committee, evaluates, appraises, and selects from the numerous available medicinal agents and dosage forms that are considered most useful for in-patient care. These medications are selected for their use in rational drug therapy, and by evaluating their efficacy, toxicity, pharmacokinetic properties, bioequivalence, pharmaceutical equivalence, therapeutic equivalence, risk for potential adverse reaction, and their cost-effectiveness. Only drug products that may be stocked in the hospital or are otherwise readily available for use will be listed in the Formulary.

PROCEDURE: (Additions and deletions in the Formulary)

1. The Pharmacy and Therapeutics Committee will determine which drugs should be added and deleted in the Formulary. The P&T Committee will rely on the input of the Formulary Subcommittee, the Anti-Infective Subcommittee, and the Medication Safety Subcommittee, or an ad hoc committee to make recommendations about which drugs or dosage forms should be listed.

2. Drugs added in the Formulary will usually be in stock within 14 days following the P&T Committee meeting. Most formulary decisions will be enacted on the first day of the month following the P&T Committee meeting. In some instances, however, it may take more time to educate staff or make operational transitions.

3. The Pharmacy and Therapeutics Committee makes the Formulary available via the Medication List in EPIC.

4. After selecting the Medication List in EPIC, type in “uf hosp” and select the “UF Hospital Formulary.” Choose the most recent contact date to access the list of medications. The formulary is the “Medication List” tab. This list may include dosage forms that are not stocked or specialty entries for specific areas of the hospital. The list defaults to an alphabetical list by drug name. Additional information can be obtained by checking the “show additional columns” box in the lower left corner of the screen. This will list each drugs “Therapeutic Class” and “Pharmaceutical Class.” All columns can be sorted to find similar drugs in these categories. In addition, a PDF version of the Formulary is available on the pharmacy website of the UF Health Bridge. There are 3 separate documents dependent upon how the information is sorted: Generic Drug Name, Brand Drug Name, or AHFS Classification. These lists are updated after each P&T meeting.

5. The Formulary is updated when EPIC entries are updated.
6. Within 7 days of the P&T Committee meeting, the Secretary will notify pharmacy stores and EPIC Willow team of any drugs that have been added to or deleted from the Formulary.

7. A Post-P&T Operations Meeting will be held the Thursday after each P&T Committee Meeting (or an alternative time when necessary) to facilitate the implementation of all formulary changes (e.g., changes to stock). This meeting will be attended by the Secretary of the P&T Committee, the Coordinators of Resource Utilization and decentralized pharmacies, representation from Information Management Services (IMS), and the Assistant Director for Inpatient Operations. Others may attend as needed (e.g., representing the Vault, etc).

8. All pharmacists, technicians, and selected nursing educators will receive additional details about the drugs that were added within the 14-day procurement period. This will be performed by an e-mail from the Secretary of the P&T Committee.

9. When a drug is considered for deletion from the Formulary, every effort to identify the primary users of the drug will be made to obtain their input on whether the drug should be deleted.

10. The stock of the deleted drug will be consolidated and sent back to the manufacturer or destroyed by the Coordinator, Resource Utilization of the Pharmacy Department.

11. Notice of additions and deletions in the Formulary and criteria for use will be published in the Drugs and Therapy Bulletin and in the “News and Announcements” section of the Pharmacy Bridge and the Formulary Update section of the Drugs & Therapy Bulletin, which is mailed to all housestaff and attendings. The Drugs & Therapy Bulletin is also posted on the Internet (http://professionals.ufandshands.org/resources/drug-information-and-pharmacy-resource-center/bulletins/)

12. The Joint Commission Medication Management standard MM.02.01.01 EP#9 states: medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information. The hospital complies with this standard by continuous review of medical literature by the P&T Committee, Formulary Subcommittee, and Medication Safety Subcommittee. Examples of medical literature reviewed primary medical journals (e.g., NEJM, Pharmacotherapy), safety literature (e.g., ISMP Medication Safety Alerts), and internet sources (e.g., FDA CDER). Efficacy and safety information identified for medications listed in the Formulary are reviewed by the above Subcommittees for any necessary action.

APPROVED BY: ___________________________ Signature on File ___________________________
UF HEALTH - SHANDS HOSPITAL
PHARMACY AND THERAPEUTICS COMMITTEE
REQUEST FOR FORMULARY ADDITION
(Please Complete, Print, Sign, and Submit via email to cannec@shands.ufl.edu)

CONTACT INFORMATION

Request By: ___________________________ Date: ___________________________

Department: ___________________________ PO Box #: _______________________

Telephone Number: ____________________ Pager Number: ___________________ 

Email Address: _________________________ ________________________________

DRUG INFORMATION

Generic Drug Name: ____________________ Trade (Brand) Name: ________________

Manufacturer: __________________________ Dosage form(s)/Strength(s) Requested: 

Proposed Mechanism of Action: __________________________ Major Adverse Effects: __________________________

ANTICIPATED IMPACT

Will this drug be used mainly for outpatients?

☐ Yes
☐ No

If outpatient therapy, would availability through outpatient pharmacy only meet your needs?

☐ Yes
☐ No

19.11
What drugs in the Formulary is/are most similar to the drug you are requesting?

Please state the perceived advantages the drug requested offers over current Formulary options:

Please estimate the annual cost impact this new product will have on the institution based on the following scale (-3 = significant cost savings, 0 = no cost impact, 3 = significant expense)

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<thead>
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<th>Cost Impact</th>
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<tr>
<td>2</td>
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<td>3</td>
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</tbody>
</table>

PROPOSED INDICATIONS FOR USE

Give specific indications including disease states for which the drug should be used. Include any prophylactic, empiric, or therapeutic uses.

Is this a first-line agent?

- Yes
- No

If not first-line, what therapy should precede this drug?
REFERENCES

Please cite references supporting the addition of the drug requested in the Formulary. Use additional pages if necessary.

Grade A:
Level 1a - Systematic review (SR) with homogeneity of Randomized Controlled Trials (RCTs)
Level 1b- Individual RCT (with narrow confidence interval [CI])
Level 1c - All patients died before treatment with therapy, but now some survive or some patients died and now none die.

Grade B:
Level 2a- SR with homogeneity of cohort studies
Level 2b- Individual cohort study (including low quality RCT)
Level 2c- Outcomes research
Level 3b- Individual case-control study

Grade C:
Level 4 - Case series (and poor quality cohort and case-control studies)

Grade D:
Level 5 - expert opinion without critical appraisal or based on pharmacology or bench research.

PLEASE COMPLETE THE ENTIRE FORM AND EMAIL TO: cannec@shands.ufl.edu

Incomplete forms will be returned. After your request is reviewed and a report evaluating the drug is prepared for the Committee, it will be placed on the agenda of the next P&T Committee meeting. You (or your representative) may choose to be present at the meeting at which the request for addition is discussed. You will be notified when your request is scheduled for review.

Signature:
Drug on Formulary is bolded; please interchange to these drugs using the appropriate conversions for the ordered drug.

**Medications Approved for Automatic Therapeutic Substitution**
Dosage Conversion Guidelines (Revised 06/2014)

<table>
<thead>
<tr>
<th>ACE INHIBITORS</th>
<th>Formulary Medication</th>
<th>Benazepril (Lotensin)</th>
<th>Fosinopril (Monopril)</th>
<th>Moexipril (Univasc)</th>
<th>Perindopril (Aceon)</th>
<th>Quinapril (Accupril)</th>
<th>Trandolapril (Mavik)</th>
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<tr>
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<table>
<thead>
<tr>
<th>ANGIOTENSIN RECEPTOR BLOCKERS (ARBs)*</th>
<th>Formulary Medication</th>
<th>Candesartan (Atacand)</th>
<th>Eprosartan (Teveten)</th>
<th>Irbesartan (Avapro)</th>
<th>Olmesartan (Benicar)</th>
<th>Telmisartan (Micardis)</th>
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*Note: Losartan (Cozaar) is also listed in the Formulary and will not be interchanged.
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.
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), pharmaeconomic 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 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.
**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.