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

g. Non-legend analgesics — at least one product of each of the following categories:
   (i) Aspirin.
   (ii) Acetaminophen.
   (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 vitamins — 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, boric epson salts for soaking, and providone-iodine ointment and solution.

l. Cotton balls, tissue, applicators, body oil or body lotion, powders, lemon glycerin 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. Blind enema.
   r. Ophthalmic lubricant.
   s. Oxygen and the equipment and supplies needed to dispense the oxygen.
   t. First aid supplies.
   v. Moisturizing sprays and ointments for treatment of pressure sores.
500—MEDICAID
RULE 59G-4 F.A.C.

w. Absorbent bladder control garments and external catheters.
x. Sterile saline solution for wound dressing.

4. Medical equipment to be available for use by the resident on a short-term basis but not for the exclusive use of the resident on a long-term ongoing basis which shall include at a minimum, the following:
   a. Wheelchairs.
   b. Geri-chairs.
   c. Walkers.
   d. Cutches and canes.
   e. Bedside commodes.

5. Medical equipment for use by or on a resident when determined medically necessary:
   a. Traction equipment.
   b. Blood pressure equipment.
   c. Oral and rectal thermometers.
   d. Protective restraints.
   e. Suction equipment.

6. Supplies made available for use by or on the resident in the facility:
   a. Patient gown.
   b. Water pitcher, drinking glass and straws.
   c. Wash pan.
   d. Emesis basin, bedpan, and urinal.
   e. Soap.
   f. Shampoo.
   g. Shaving supplies.
   h. Straws.
   i. Denture cups.
   j. Nail care equipment.
   k. Toothpaste and denture powder.
   l. Deodorant.

Revised February 1995
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
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.
Important component of the medication use process in a hospital

- GOAL: promote rational, appropriate, safe use of drugs
- Effective way to control drug expenses
- Dynamic and comprehensive process

The 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.

**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.

**The Joint Commission Standard MM 02.01.01** Medications available for dispensing or administration are selected, listed, and procured based on criteria.

- Formulary is established by the medical staff
- Formulary consists of a list of medications, strengths and dosage forms available in the hospital.
  - If formulary – stocked in pharmacy regardless of utilization (e.g., Dantrium for malignant hyperthermia)
  - In non-formulary – not stocked
- Written criteria are used to determine additions/deletions to the formulary. Minimum criteria:
  - Indication for use
  - Effectiveness (including propensity for medication errors, abuse potential, sentinel events)
  - Cost
- Periodically updated based on emerging safety and efficacy information
- Reviewed annually
- Policies address approval & procurement of non-formulary medications
Policies address medication shortages and outages
- Communicating with appropriate prescribers and staff;
- Developing approved substitution protocols;
- Educating appropriate LIPs, health care professionals and staff about these protocols; and
- Obtaining medications in the event of a disaster

Policies address Formulary Interchange or Therapeutic Equivalents
- Used to direct prescribing
- Educate appropriate LIPs, health care professionals and staff
- Pharmacy is authorized to purchase and dispense the most cost-effective product, or
- P&T committee designates a preferred product for formulary addition and other drugs are deleted from the formulary

Reference policies:
9.9   Unlabeled drug (is it legal to use drug outside of FDA approved labeling?)
9.13  Formulary request form
19.16 Sample formulary substitutions
19.20 Algorithm
19.21 Reference on the Formulary System
TITLE: P&T COMMITTEE STATEMENT ON UNLABELED USES OF FDA APPROVED DRUGS

POLICY:

The P&T Committee believes that prescribers may use drugs outside of their FDA approved product labeling as long as relevant clinical literature supporting that use is available and readily retrievable. To help optimize safety and effectiveness of a drug prescribed for an unlabeled use, pharmacists, nurses, and other health professionals are encouraged to confer with the prescriber prior to administration of that medication. Further, the Committee believes that the package insert is informational only and serves as a guide for prescribing drugs.

BACKGROUND:

There is often concern and confusion regarding the legality of using drugs outside their official package insert labeling. The P&T Committee has been asked to develop recommendations on this issue to guide practitioners in the appropriate manner in which to handle this issue. To help bring everyone to a common understanding, this topic will be briefly reviewed based on FDA recommendations.

An “unapproved” use of a drug simply reflects use outside the manufacturer’s promotional labeling (package insert). Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug’s safety and effectiveness have been established through clinical trials and which the FDA has approved. These are referred to as “approved” uses. The FD&C Act does not, however, limit the way a physician may use an approved drug.

An unapproved use would probably best be described as an “unlabeled” use. The literature may support an unlabeled use of a drug for a patient population, dose, regimen or indication not stated in the package insert. In this case, use of the drug would be appropriate. The FD&C Act does not regulate the practice of medicine only the way drugs can be promoted.

A drug generally becomes approved for a particular use through efforts of the manufacturer. If the manufacturer was not driving the process through sponsorship of extensive clinical trials new uses would not become approved by the FDA. This process takes time and money and usually occurs only if the manufacturer considers it economically feasible. Examples of well recognized uses of drugs that are still considered unapproved include demeclocycline for SIADH, iron dextran for use as an infusion, phenytoin infusion for seizures, meperidine for shaking chills associated with amphotericin B, sucralfate suspension for mucositis, terbutaline for inhibition of labor, and tetracycline for Lyme disease. These uses may never become approved by the FDA because the manufacturers are not actively pursuing the indication.

The FDA states that the package insert is informational only as it relates to medical practice. The FDA tries to assure that prescription drug information in the package insert reflects the complete data on safety and effectiveness on which approved uses are based.
Reference

PROCEDURE:

1. When prescribing a drug for an unlabeled use (i.e., unlabeled indication, dosage, route, etc.), the prescriber should ensure that relevant clinical literature supporting that use is available and readily retrievable.

2. Nurses, pharmacists and other health care professionals should confer with the prescriber if a drug is prescribed for an obscure or unfamiliar unlabeled use.

Shands Jacksonville Medical Center
EXAMPLE: FORMULARY PROCESS

PURPOSE
To define the process by which medications are selected, procured, and used throughout the institution. This process is to be consistent with legal requirements, HCA purchasing guidelines, and JCAHO standards.

SCOPE
This is a hospital-wide policy and procedure applicable to all established departments.

POLICY
The P&T Committee is responsible for establishing and maintaining a Formulary of medications for use in the institution. All formulary medications are reviewed at least annually based on emerging information pertaining to safety and efficacy. Non-Formulary medications may be used, consistent with outlined procedures.

BACKGROUND
A formulary is defined as a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of the medical staff.

The Pharmacy and Therapeutics Committee has the following formulary objectives.

1) Arrange to have needed drugs in stock and ready to use before the physician writes orders.
2) Meet all JCAHO standards for hospital formularies in a cost-effective manner.
3) Utilize the expertise of the medical staff to establish appropriate usage guidelines for new drugs. Conduct drug use evaluations and medical staff education based upon the established guidelines.
PROCEDURE

The P&T Committee reviews all proposed formulary additions and deletions. Proposed changes can be generated from a variety of sources, including, but not limited to:

1) Requests from medical staff physicians.
2) New medications identified by the pharmacy as potential additions.
3) Medications identified by the pharmacy as potential deletions due to non-use, discontinuation by the manufacturer, or safety related issues.
4) P&T Committee activities, such as Drug Use Review.
5) Routine pharmacy review of non-formulary medication orders.
6) Recommendations from other NFRMC committees.

When a physician identifies a drug for possible addition to the formulary, they should contact the pharmacy for a Formulary Addition Request Form, complete it and return it to the Director of Pharmacy.

Criteria for Additions to the Formulary

- **Indication for use:** Primary consideration will be given to those drugs determined to be useful for the disease or conditions treated in the hospital and the indications for the use of these drugs.

- **Effectiveness:** Primary consideration will be given to the relative safety and efficacy of drugs. Drugs are included in the formulary as generic entities. Selection of the source of generic drugs is delegated to the Pharmacy Department unless the committee identifies specific issues with bioequivalence. Such exceptions will be noted in the formulary.

- **Risk:** It is recognized that all drug therapy has attendant risk. Initial evaluation by the committee is based on the documented adverse event profile and risk potential; this is especially true with new drugs. Ongoing monitoring of the adverse event profile in this hospital and in the literature will be used to evaluate all formulary drugs. Risk includes potential for error in Prescribing, Preparation, Dispensing, Administration, and potential for abuse.

- **Cost:** Secondary consideration will be given to acquisition cost and other costs associated with the use of a particular drug. Relative cost within drug classes will be considered. It is acknowledged that drug cost may in some cases have an inverse relationship to overall treatment costs.

When needed, the P&T Committee may make recommendations to the medical staff regarding appropriate use of the medication. This would most often be applied to medications regarded as alternatives to standard medications. The usage guidelines can be used as the basis for future Drug Use Evaluations. The Pharmacy and Therapeutics Committee may solicit opinions from other medical specialists when appropriate. The
information will be reviewed at a regularly scheduled meeting and will consider patient need and safety, effectiveness, risk and cost. The above general criteria will be used.

Drug Monitoring Process

A current formulary monograph will be readily accessible via MicroMedex to physicians, nurses and other staff involved in monitoring patients prior to formulary approval of a new medication.

Formulary Communication and Publication

P&T Committee Formulary actions and recommendations are published in the P&T Bulletin. The bulletins are distributed to all medical staff members and hospital clinical departments.

An on-line formulary is available in the Computer Library and is accessible to all Hospital computer users. The on-line formulary document will contain a list of all approved formulary medications sorted by therapeutic class.

NON-FORMULARY MEDICATIONS

Generally, every effort should be made to utilize drugs currently on the formulary prior to obtaining non-formulary drugs from the outside. Upon receipt of a non-formulary order, the pharmacist will determine if the drug is covered by a current substitution protocol or if there is a reasonable alternative product on the formulary. The prescriber will be contacted to recommend an alternative (see Non-Formulary Approval and Procurement Procedure) and will be informed of any delay that is anticipated to secure the medication from an alternate source. All non-formulary orders are reviewed by the P&T Committee as part of the medication use evaluation process.
This form should be completed and returned to the Department of Pharmacy. The P&T committee requests that you (or your representative) attend the meeting to discuss your reason(s) for recommending this drug for formulary addition. You will be notified when your request is scheduled for review by the Pharmacy and Therapeutics (P&T) Committee. Action can only be taken if you attend.

1. Generic (nonproprietary) name:________________________________________
2. Trade (brand) name:_________________________________________________
3. Manufacturer:______________________________________________________
4. Dosage form(s) strength(s) requested:___________________________________
5. Comparable Drug(s) on the hospital formulary:___________________________
6. Which drugs listed in #5 above may be deleted from the hospital formulary?
   ___________________________________________________________________
   ___________________________________________________________________

7. Please list significant advantages (e.g., efficacy, safety, cost, etc.) that this product offers over currently available formulary products. Include or cite supporting published references.
   ___________________________________________________________________
   ___________________________________________________________________
   ___________________________________________________________________
   ___________________________________________________________________

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

<table>
<thead>
<tr>
<th>-3</th>
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<th>-1</th>
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<td>moderate cost savings</td>
<td>minimal cost savings</td>
<td>neutral</td>
<td>minimal added expense</td>
<td>moderate added expense</td>
<td>significant added expense</td>
</tr>
</tbody>
</table>

   9. Give specific indications (FDA approved and non-approved), including disease state(s), for which you feel the drug should be utilized.
   ___________________________________________________________________

   10. Is this a first line drug? _____ YES  _____ NO
       If no, what should precede the use of this drug?____________________

   11. How did your first become aware of this drug? Please check (√) all that apply.
       ____Scientific study in medical journal  ____ Advertisement in medical journal
       ____ Scientific meeting  ____ Manufacturer-sponsored symposium
       ____ Non-physician health care professional
       ____ Pharmaceutical sales representative
       ____ Fellow faculty member or colleague
       Other: ________________________
12. For how many patients have you prescribed this agent?
   _____ 0 to 5   _____ 26 to 100
   _____ 6 to 25   _____ greater than 100

13. Have you participated, or are you currently participating in a clinical trial of the requested agent?
   _____ YES   _____ NO

14. Are you participating in other trial sponsored by the manufacturer of the agent being requested?
   _____ YES   _____ NO

15. Which of the following most influenced you to initiate this formulary addition request?
   ____ Pharmaceutical sales representatives  ____ Favorable clinical experience
   ____ Weight of the scientific literature  ____ Other ____________

16. Which of the following justifications for formulary admission do you feel apply to the agent being requested? Please check (√) all that apply.
   ____ Represents a unique pharmacologic/therapeutic compound (FDA Class 1A).
   ____ Represents a significant therapeutic advantage over similar formulary agents.
   ____ Is a necessary alternative.
   ____ Is equally efficacious and safe as current formulary agents and is less expensive.
   ____ Has an improved safety profile over current formulary agents.
   ____ Other ___________________________________________________________________

Submitted by (signature): _________________________ Date: __________________
Print Name:______________________ Department/Ext.: ______________________

I approved this submission to the Pharmacy and Therapeutics Committee.
Approved by:____________________ Date:____________________________

(Department Chairperson or Director)
EXAMPLE: FORMULARY SUBSTITUTION

PURPOSE
To describe the formulary substitution process.

SCOPE
This is a hospital-wide policy and procedure applicable to all established departments.

POLICY
Formulary substitution is defined as the exchange of an ordered drug product for a different drug composition or drug entity possessing substantially the same therapeutic effects. Formulary substitution may only be practiced according to those protocols recommended by the Pharmacy and Therapeutics Committee and adopted by the medical staff (see Appendix 1).

The physician may override or prevent the substitution by including a statement such as “Do not substitute” or “Medically necessary” in the order.

The P&T Committee will determine what level of physician notification is required for each protocol based upon its therapeutic significance.

PROCEDURE

Pharmacy Procedure:
When a product substitution is made, the pharmacist will do the following:

1) Enter the order for the approved substitute drug into the computer system.

2) Enter "Substituted for (drug originally ordered)" in the order comments field.

3) If the substitution protocol is defined as "Notification required" a Substitution Notice is filled out and sent to the nursing unit with the first dose of the drug.
<table>
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<tr>
<th>FORMULARY CLASS</th>
<th>FORMULARY AGENT(s)</th>
<th>SUBSTITUTION</th>
<th>NOTIFICATION (Yes/No)</th>
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<tr>
<td>1st generation cephalosporins</td>
<td>Cefazolin (Ancef®)</td>
<td>Cefazolin 1 gm IV q8h substituted for Cefazolin 1gm IV q6h Cefazolin 2 gm IV q8h substituted for Cefazolin 2 gm IV q6h</td>
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<td>2nd generation cephalosporins</td>
<td>Cefotetan (Cefotan®)</td>
<td>Cefotetan 1gm IV q12h substituted for Cefoxitin 1gm IV q6h or q8h Cefotetan 2gm IV q12h substituted for Cefoxitin 2 gm IV q6h or q8h</td>
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<td>3rd generation cephalosporins</td>
<td>Ceftriaxone (Rocephin®)</td>
<td>Ceftriaxone 1 gm iv q24h substituted for Cefotaxime 1 gm iv q8h Ceftriaxone 1 gm iv q24h substituted for Cefotaxime 1 gm iv q12h Ceftriaxone 2 gm iv q24h substituted for Cefotaxime 2 gm iv q8h</td>
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<tr>
<td>Penicillinas e-resistant penicillins</td>
<td>Oxacillin Nafcillin - pediatrics pts. only Dicloxacillin - oral</td>
<td>Oxacillin substituted on a mg/mg basis for nafcillin &amp; methicillin Dicloxacillin substituted on a mg/mg basis for oral nafcillin, oxacillin, &amp; cloxacillin (Note: the administration schedule will remain the same)</td>
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<tr>
<td>Fluoroquinolones</td>
<td>Levofloxacin (Levaquin®) Ciprofloxacin (Cipro®)</td>
<td><strong>Levaquin 250 mg IV or po q24h substituted for:</strong> Cinoxacin (Cinobac®) 250mg po qd Ciprofloxacin 250 mg po bid Ciprofloxacin 200 mg IV q12h Ofloxacin (Floxin®) 200 mg IV or po q12h Norfloxacin (Noroxin®) 400 mg po bid Enoxacin (Penetrex®) 200 mg po bid Sparfloxacin (Zagam®) 200 mg po qd <strong>Levaquin 500 mg IV or po q24h substituted for:</strong> Cinoxacin 500mg po bid Ciprofloxacin 500 mg or 750mg po bid Ciprofloxacin 400 mg IV q12h Ofloxacin 300 mg or 400 mg IV or po q12h Lomefloxacin (Maxaquin®) 400 mg po qd Enoxacin 400 mg po bid</td>
<td>Yes</td>
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<td>Oral potassium products</td>
<td>KCL 20 mEq/15ml elixir (Kaochlor-SF®) KCL 40 mEq/30ml elixir (Kaochlor-SF®) KCL 20 mEq powder pts. (K-LOR®) KCL 8 mEq &amp; 10 mEq capsules (Micro-K®) Potassium bicarbonate 25 mEq (KLORECON/EF®) equiv. K-lyte</td>
<td>KCL elixir or packets (dissolved in H2O) will be reserved for STAT orders, NGT orders, or situations where odd doses are required All orders for potassium chloride in multiples of 10mEq or 8 mEq will be filled with either Micro-K 10 mEq caps or Micro-K 8 mEq caps K-lyte will be reserved for clinical situations where the chloride salt of potassium would be inappropriate.</td>
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<td>Sedative/hypnotics</td>
<td>Temazepam (Restoril®)</td>
<td><strong>Temazepam 15 mg substituted for:</strong> Flurazepam (Dalmane®) 15 mg Triazolam (Halcion®) 0.125 mg</td>
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<td>FORMULARY CLASS</td>
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<td>SUBSTITUTION</td>
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<td>Oral vitamins</td>
<td>Multivitamin</td>
<td>MVI, MVI/iron, MVI/minerals, MVI/zinc, Centrum®, Centrum Silver®, Stress-600®, Stress-600/zinc®, Berocca Plus®, Ocuveite®, Os-Cal Fortified®, Vicon Forte®, B complex with C.</td>
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<td>Centrum Jr. with iron</td>
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Theophylline infusions

Premixed theophylline solution: 800 mg theophylline in 1000 ml D5W (equiv. to 1000 mg aminophylline in 1000 ml D5W)

Theophylline solution will be used instead of aminophylline whenever possible. (Note: Specialized solutions will be prepared for patients with special needs)

No

Proton-pump inhibitors

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<tr>
<th>Indication</th>
<th>Pantoprazole (Protonix®)</th>
<th>Omeprazole (Prilosec)</th>
<th>Rabeprazole (Aciphex)</th>
<th>Lansoprazole (Prevacid)</th>
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H₂-receptor antagonists

Famotidine 20 mg po bid will be substituted for:
- Cimetidine (Tagamet®) 800 mg qd, 300 mg qid, and 400 mg bid
- Nizatidine (Axid®) 150 mg bid
- Ranitidine (Zantac®) 150 mg po bid

Famotidine 20 mg iv q12h will be substituted for:
- Cimetidine 300 mg IV q6-8h
- Ranitidine 50 mg IV q8h or q12h

Famotidine 20 mg iv q24h will be substituted for:
- Ranitidine 50 mg iv q24h

Yes

Estrogen

Climara® will be substituted for Estraderm® and Vivelle®

No
<table>
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<tr>
<th>FORMULARY CLASS</th>
<th>FORMULARY AGENT(s)</th>
<th>SUBSTITUTE</th>
<th>NOTIFICATION (Yes/No)</th>
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<tbody>
<tr>
<td>patches</td>
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<tr>
<td>HMG-CoA reductase inhibitors</td>
<td>Simvastatin (Zocor®)</td>
<td><em>Zocor 20 mg po qd will be substituted for:</em> Atorvastatin (Lipitor®) 10 mg Lovastatin (Mevacor®) 10 - 80 mg Pravastatin (Pravachol®) 10 - 40 mg Fluvastatin (Lescol®) 20 - 80 mg Cerivastatin (Baycol®) 0.3 - 0.4 mg <em>Zocor 40 mg po qd will be substituted for:</em> Atorvastatin (Lipitor®) 20 mg Zocor 80mg po qd will be substituted for Atorvastatin (Lipitor®) 40 - 80 mg</td>
<td>Yes</td>
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<tr>
<td></td>
<td></td>
<td><em>Montelukast 10 mg po qd will be substituted for:</em> Zafirlukast (Accolate®) 20 mg po bid Zileuton (Zyflo®) 600 mg po qid</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Montelukast (Singular®)</td>
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<td></td>
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<tr>
<td>Over the counter products</td>
<td></td>
<td>Any alternative formulary over the counter product.</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-sedating antihistamines</td>
<td>Loratadine (Claritin®)</td>
<td>Allegra® 30mg BID</td>
<td>Yes</td>
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<tr>
<td></td>
<td></td>
<td>Allegra® 60mg BID</td>
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<td></td>
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<td>Allegra® 180mg QD</td>
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<td></td>
<td></td>
<td>Allegra-D® 1 tablet BID</td>
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<tr>
<td></td>
<td></td>
<td>Zyrtec® 2.5mg QD</td>
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<td>Zyrtec® 5mg QD</td>
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<td></td>
<td>Zyrtec® 10mg QD</td>
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<td></td>
<td>Zyrtec-D® 1 tablet QD</td>
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<td></td>
<td></td>
<td>Claritin® 10mg QD, Pseudoephedrine 120 mg q12h</td>
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<td></td>
<td></td>
<td>Claritin® 5mg QD</td>
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<td>Claritin® 10mg QD</td>
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<td>Zyrtec-D® 1 tablet BID</td>
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<td>Zyrtec-D® 1 tablet BID</td>
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<td></td>
<td>Claritin® 10mg QD, Pseudoephedrine 30mg QID</td>
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<td></td>
<td></td>
<td>Claritin® 10mg QD, Pseudoephedrine 120 mg q12h</td>
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<td></td>
<td></td>
<td>Clarinex 5mg QD</td>
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<td></td>
<td></td>
<td>Claritin-D 12-hour® 1 tablet BID</td>
<td></td>
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<td></td>
<td>Claritin® 10mg QD, Pseudoephedrine 120 mg q12h</td>
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<td>FORMULARY CLASS</td>
<td>FORMULARY AGENT(s)</td>
<td>SUBSTITUTION</td>
<td>NOTIFICATION (Yes/No)</td>
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<td></td>
<td>Claritin-D 24-hour® 1 tablet QD</td>
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<td></td>
<td>Claritin® 10mg QD, Pseudoephedrine 120 mg q12h</td>
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<tr>
<td>Controlled</td>
<td>Percocet -5® (oxycodone 5 mg/apap 325 mg)</td>
<td><strong>Percocet-5® will be substituted for:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>Substances</td>
<td></td>
<td>Tyloxx® capsules (oxycodone 5 mg/apap 500 mg)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Percodan® tablets (oxycodone 5 mg/asa 325mg)</td>
<td></td>
</tr>
<tr>
<td>Controlled</td>
<td>Lortab® 5/500 (hydrocodone 5mg/apap 500 mg)</td>
<td><strong>Lortab® 5/500 will be substituted for:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>Substances</td>
<td>Lortab® 7.5/500 (hydrocodone 7.5 mg/apap 500 mg)</td>
<td>Vicodin® (hydrocodone 5mg/apap 500 mg)</td>
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</tr>
<tr>
<td></td>
<td>Lortab® 10/500 (hydrocodone 10 mg/apap 500 mg)</td>
<td><strong>Lortab® 7.5/500 will be substituted for:</strong></td>
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<tr>
<td></td>
<td></td>
<td>Vicodin® ES (hydrocodone 7.5 mg/apap 750 mg)</td>
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<td></td>
<td><strong>Lortab® 10/500 will be substituted for:</strong></td>
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<td></td>
<td></td>
<td>Lorcat® 10/650 (hydrocodone 10 mg/apap 650 mg)</td>
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<tr>
<td>Carbapenems</td>
<td>Meropenem (Merrem®)</td>
<td>When the pharmacist receives an order for Primaxin®, Merrem® will be</td>
<td>Yes</td>
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<td></td>
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<td>substituted based on the patient’s renal function:</td>
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<td></td>
<td><strong>(Cler) \hspace{1cm} \textit{Dose}</strong></td>
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<td></td>
<td></td>
<td>&gt;50 ml/min \hspace{1cm} 1 gm iv q8h</td>
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<td></td>
<td></td>
<td>26-50 ml/min \hspace{1cm} 1 gm iv q12h</td>
<td></td>
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<td></td>
<td></td>
<td>10-25 ml/min \hspace{1cm} 500 mg iv q12h</td>
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<tr>
<td></td>
<td></td>
<td>&lt;10 ml/min \hspace{1cm} 500 mg iv q24h</td>
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</tr>
<tr>
<td>Controlled</td>
<td>Fioricet</td>
<td>All orders for Fiorinal will be substituted with Fioricet with the same dosing</td>
<td>Yes</td>
</tr>
<tr>
<td>Substances</td>
<td></td>
<td>schedule</td>
<td></td>
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<tr>
<td>Estrogen</td>
<td>Premarin</td>
<td>All orders for Estrace vaginal cream will be substituted with Premarin</td>
<td>Yes</td>
</tr>
<tr>
<td>Vaginal Cream</td>
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<td>vaginal cream</td>
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<tr>
<td>Bronchodilators</td>
<td>Racemic albuterol</td>
<td>All orders for levalbuterol will be substituted with racemic albuterol as</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>\textit{Orders for levalbuterol 1.25 mg will be substituted with 2.5 mg albuterol}</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>\textit{Orders for levalbuterol 0.63 mg will be substituted with 1.25 mg albuterol}</td>
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<td></td>
<td></td>
<td>\textit{Orders for levalbuterol 0.31 mg will be substituted with 0.63 mg of albuterol}</td>
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</table>
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.

19.21
GUARDING PRINCIPLES

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

- 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 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.
1. Academy of Managed Care Pharmacy, Concepts in Managed Care Pharmacy Series - Formulary Management (Alexandria, VA: 1998).


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.