



# MARYLAND PHARMACY PROGRAM

## Medicaid - Pharmacy Assistance – Pharmacy Discount

No. 10 Revised

# ADVISORY

*In an effort to give timely notice to the pharmacy community concerning important pharmacy topics, the Department of Health and Mental Hygiene's (DHMH) **Maryland Pharmacy Program (MPP)** has developed the **Maryland Pharmacy Program Advisory**. To expedite information timely to the pharmacy and prescriber communities, an email network has been established which incorporates the email lists of the Maryland Pharmacists Association, EPIC, CARE, Long Term Care Consultants, headquarters of all chain drugstores and prescriber associations and organizations. It is our hope that the information is disseminated to all interested parties. If you have not received this email through any of the previously noted parties or via DHMH, please contact the MPP representative at 410-767-5395.*

### **MedWatch Requirement for Brand Medically Necessary Prescriptions**

Effective October 15, 2004, prescribers must complete the Department of Health and Mental Hygiene (DHMH) Medwatch form and forward the completed copy to the Maryland Pharmacy Program for its review before the Program will reimburse at the brand rate for prescriptions dispensed as brand medically necessary. This is to comply with recent regulation amendments to COMAR 10.09.03.07 H(3) requiring that a prescriber file an official report of an adverse event or problem regarding a generic drug product. This report must be submitted and approved before the Program will reimburse at the allowable cost of the corresponding brand name product. A copy of the DHMH Medwatch form is included with this Advisory and can also be obtained from DHMH's Maryland Pharmacy Program website as listed below:

- Maryland Pharmacy Program website <http://dhmh.state.md.us/mma/mpap/fda.htm>

The FDA requires bioavailability tests on generic drugs to determine whether they are bioequivalent to the branded product. This information is published in the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book". There is no valid reason why a generic drug rated as bioequivalent should not be equally as effective as the brand. The

purpose of requiring a DHMH Medwatch form is to allow DHMH to first screen the validity of the adverse event before forwarding the information to the FDA to investigate the rare cases where an ingredient in a generic formulation is causing an adverse reaction or where a specific formulation is causing a problem. The Program will not pay for the brand solely because the patient does not want a generic drug. The situation where a recipient is allergic to all generics is not acceptable and will not be honored by the Program. In the context of this policy, “Brand Medically Necessary” is defined as necessity to prescribe and dispense a brand name medication when use of a generic product has resulted in a) Adverse Reaction(s) to the generic, b) Allergic Reaction(s) to the generic, or c) Therapeutic Failure of the generic:

a) Adverse Reactions caused by a generic must meet one of the following criteria:

1. Life Threatening
2. Hospitalization
3. Disability
4. Required intervention to prevent impairment or damage

b) Allergic Reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.

c) Therapeutic Failure is defined as, clinical failure due to the recipient’s suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

### **For the Prescriber**

To request an over-ride for a brand medically necessary prescription, the prescriber must complete and sign the DHMH Medwatch form and fax a copy to the Maryland Pharmacy Program at 410-333-5398. The prescriber should write “MEDWATCH FORM SUBMITTED” in addition to “BRAND MEDICALLY NECESSARY” on the prescription order to indicate to the dispensing pharmacist that the required documentation has been submitted. The Program will review the completed Medwatch form and if there is a legitimate problem requiring use of the brand product, the Program will approve the request. The Program will advise the prescriber of the outcome of the review and forward a copy of the Medwatch form to the FDA for investigation.

## **For the Pharmacy**

Upon receipt of a prescription order noted by the prescriber with “MEDWATCH FORM SUBMITTED” and “BRAND MEDICALLY NECESSARY”, the pharmacist should submit the claim on-line with a DAW indicator of “1”. If the prescriber has faxed the DHMH Medwatch form to the Program and it is approved, a preauthorization will have been entered into the system and the claim will pay on-line. If not, the claim will deny with the message to call for preauthorization. The pharmacist should call the Department at 410-767-1755 (pharmacies outside the Baltimore area can call toll-free via the recipient pharmacy hotline at 800-492-5231 option 3) during normal business hours to obtain preauthorization before dispensing the prescription. If another generic version is available, the Program may require a trial with another generic before approving the brand name product. After preauthorization is entered into the system, the pharmacy may resubmit the claim and be paid on-line at the rate of the particular brand being dispensed. Subsequent prescriptions for the brand submitted with DAW = “1” will pay on-line without a rejection.

## **Emergency Supply: Outside of Normal Business Hours**

In the case of a true emergency, outside of normal business hours, the First Health help-desk can issue a one-time preauthorization for a three-day emergency supply if the words, “MEDWATCH FORM SUBMITTED” and “BRAND MEDICALLY NECESSARY” are written on the prescription order.

- ❖ For Schedule II Narcotic Prescriptions, a three-day supply of the brand name drug may be dispensed; however:
  - After three days, whether the brand is approved or denied, a new prescription order will have to be written for the remaining portion of the drug regimen.
  - If the patient elects not to be “inconvenienced” by obtaining a new prescription order, the patient may receive the full amount of the generic prescription at the time the prescription order is presented.
- ❖ For Non-Schedule II Narcotic Prescriptions, a three-day supply of the brand name drug may be dispensed:
  - After three days, if the brand name drug is approved, the remaining portion of the brand name drug prescription may be dispensed.

- However, if the brand name drug is denied, the remaining portion of the prescription may be dispensed with the generic product.

**In all situations, when an emergency supply is dispensed, the dispensing fee to the pharmacy will be \$2.69 (brand name drug) and no co-pay will be charged to the patient.**

#### **Excepted Drugs**

According to the July 2004 Maryland Board of Pharmacy Newsletter, the drug products listed below are non-substitutable in Maryland. The Maryland Medicaid Program does not assign an interchangeable drug cost (IDC) to non-substitutable drug products and consequently the MedWatch requirement would not apply.

Phenytoin Sodium Extended Oral Capsules 100mg

Primidone Oral Tablets 250mg

Valproic Acid Oral Capsules 250mg

Theophylline Extended Release Oral Tablets 100mg, 200mg, 300mg

Warfarin Sodium Oral Tablets 2mg, 2.5mg and 5mg

**NOTE:** Carbamazepine Oral Tablets 200mg are on the list of Excepted Drugs but the Lemmon Company's (now Teva) Epitol may be interchanged for Tegretol. The Program assigns an IDC price using Epitol and the Medwatch form would be required for payment of Tegretol at the brand price.

Questions concerning this Advisory should be directed to the Division of Pharmacy Services, 410-767-1455.