STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Robert L. Ehrlich, Jr., Governor – Michael S. Steele, Lt. Governor – S. Anthony McCann, Secretary

Office of Operations, Eligibility & Pharmacy
Medical Care Programs

Joseph E. Davis
Executive Director

MARYLAND MEDICAL ASSISTANCE PROGRAM
Pharmacy Transmittal No. 176
October 8, 2004

TO: Physicians, Pharmacies

FROM: Joseph E. Davis, Executive Director
Office of Operations, Eligibility and Pharmacy

RE: **MedWatch Requirement for Brand Medically Necessary Prescriptions**

Effective October 15, 2004, prescribers must complete a Food and Drug Administration (FDA) MedWatch form and forward a 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 product problem regarding a generic drug product with the FDA before the Program will reimburse at the allowable cost of the corresponding brand name product. A copy of a MedWatch form is included with this transmittal and can also be obtained from the FDA website.

The FDA conducts tests on generic drugs to determine whether they are bioequivalent to the branded product and publishes this information 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 as equally effective as the brand. The purpose of requiring the MedWatch form is to allow 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 generic. No recipient is allergic to all generics so this explanation will not be honored by the Program.

In the context of this policy, Brand Medically Necessary is defined as the 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 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 to indicate to the dispensing pharmacist that the required documentation has been submitted. The Program will review the MedWatch form when it is received and if there is a legitimate problem requiring use of the brand product, approve the request. The Program will then forward a copy of the MedWatch form to the FDA for investigation and advise the prescriber of the outcome of the review.

For the Pharmacy

Upon receipt of a prescription noted by the prescriber with "MEDWATCH FORM SUBMITTED" and "BRAND MEDICALLY NECESSARY", the pharmacist should submit the prescription on-line with a DAW indicator of "1". If the prescriber has faxed the MedWatch form to the Program and it is approved, a preauthorization will be entered into the system and the claim will pay on-line. If not, the claim will reject 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 can 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. 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 days supply.

Exceptions

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

Carbamazepine Oral Tablets 200mg are on the list 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 transmittal should be directed to the Division of Pharmacy Services, 410-767-1455.

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

FDA USE ONLY
Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier
In confidence

2. Age at Time of Event:
or
Date of Birth:

3. Sex
☐ Female
☐ Male

4. Weight
____ lbs
or
____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(mo/day/yr)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Other: _____

3. Date of Event *(mo/day/year)*

4. Date of This Report *(mo/day/year)*

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

C. SUSPECT MEDICATION(S)

1. Name *(Give labeled strength & mfr/labeler, if known)*
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1
#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # *(if known)*
#1
#2

7. Exp. Date *(if known)*
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# *(For product problems only)*
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10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Type of Device

3. Manufacturer Name, City and State

4. Model #
Catalog #
Serial #
Lot #
Expiration Date *(mo/day/yr)*
Other #

5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☐ Other:

6. If Implanted, Give Date *(mo/day/yr)*

7. If Explanted, Give Date *(mo/day/yr)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mo/day/yr)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. REPORTER *(See confidentiality section on back)*

1. Name and Address

Phone #

2. Health Professional?
☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

-or-

FAX to:
1-800-FDA-0178

FORM FDA 3500 (12/03) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics
- Medication errors

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

Report SERIOUS adverse events. An event is serious when the patient outcome is:

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- Death
- Life-threatening *(real risk of dying)*
- Hospitalization *(initial or prolonged)*
- Disability *(significant, persistent or permanent)*
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section C for all products except medical devices
- Attach additional blank pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

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Important numbers:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone or for more information
- 1-800-822-7967 -- For a VAERS form for vaccines

To Report via the Internet:

http://www.fda.gov/medwatch/report.htm

FORM FDA 3500 (12/03) (Back) **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787