

# Mississippi Medicaid Pharmacy Program Quarterly News

Fall 2007

Published Quarterly by Health Information Designs, Inc

Welcome to the Fall 2007 edition of the "Mississippi Medicaid Pharmacy Program Quarterly News," published by Health Information Designs, Inc., (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community

## Did You Know?

- Mississippi Medicaid's annual budget is \$4 billion. Of the total budget, Mississippi's share is about \$1 billion and the federal share is about \$3 billion.
- Of this \$4 billion, \$417 million was spent on pharmacy benefits during fiscal year 2006, down from \$692 million during FY2005. One factor in the decrease of pharmacy expenditures was the initiation of Medicare's Part D program.
- DOM averages about 400,000 to 450,000 prescription claims per month, down from about 1 million pharmacy claims per month during 2005.
- DOM reimburses Pharmacy claims approximately:
  - \$30-35 million a month
  - \$1.15 million a day
  - \$47,916.67 an hour
  - \$798.62 a minute
  - \$13.31 a second
- Behind the scenes, HID, as the DOM contractor:
  - Processes 700 automatic and manual prior authorization requests per day on average
  - Processes about 40 to 45 percent of PA approvals electronically, which requires no paperwork from the prescriber or pharmacy
  - Assists over 100 providers each day through our Jackson area call center
- Common reasons for denial of manual PA requests include:
  - No prescriber signature
  - No diagnosis provided
  - No medical justification provided



Visit HID's Mississippi Division of Medicaid Prior Authorization Webpage, [www.hidmsmedicaid.com](http://www.hidmsmedicaid.com)

## RxPert™ Electronic PA System

RxPert is an automatic prior authorization system that operates behind the scenes to approve prescriptions for Medicaid beneficiaries. Saving time for both providers and beneficiaries, electronic PA is an important component of the prior authorization process. HID's RxPert has been in place for DOM for over two years and has successfully reviewed over 680,000 PA requests for DOM providers and beneficiaries.

### Inside this issue: Page

Mississippi Medicaid Stats	1
RxPert Electronic PA	1
FDA—'New Look at Old Drugs'	2-3
Medicare Part D and Medicaid	4
Conjunctivitis	5
HID Staff / Contact Information	6

## FDA Action on Unapproved Products

In June 2006, the FDA announced an initiative to become more stringent on makers of unapproved drugs by issuing "Marketed Unapproved Drugs – Compliance Policy Guide," also known as the 2006 CPG. Most prescription drugs marketed in the U.S. have been reviewed and approved as required by the FDA. However, some older agents are "FDA unapproved" prescription drugs and are marketed by companies, prescribed by physicians, and taken by patients. The FDA estimates that there are several hundred different unapproved prescription drug active ingredients currently on the market.

### History of Safety Regulation

Before enactment of the Federal Food, Drug and Cosmetic Act of 1938, drugs could be marketed in the United States as long as a drug's label did not present false information regarding the drug's strength and purity. The Federal Food, Drug and Cosmetic Act first established the requirement that a manufacturer has to prove the safety of a drug before the manufacturer could market it in the United States.

In accordance with that statute, drugs marketed before the passage of the Federal Food, Drug and Cosmetic Act were "grandfathered" so that manufacturers were allowed to continue to market them unless evidence was developed to indicate that they were not safe, provided they do not change the representations on the drugs' labels. These medications are commonly referred to as pre-38 drugs. However, once a manufacturer changed the representation on a pre-38 drug's label, that drug was considered by the Food and Drug Administration to be a "new drug" and the manufacturer was required to prove that the drug was safe for its intended use.

### DESI—Regulation of Efficacy

In 1962, the Federal Food, Drug and Cosmetic Act was amended to require that drugs sold in the United States be regulated more closely, requiring new drugs to be shown by adequate studies to be both safe and effective before they can be marketed. This legislation also applied retroactively to all drugs approved as safe from 1938 to 1962, known as pre-62 drugs. These pre-62 drugs were permitted to remain on the market while evidence of their effectiveness was reviewed. The program established under which the Federal Drug Administration (FDA) would review the effectiveness of drugs approved between 1938 and 1962 was named the Drug Efficacy Study Implementation (DESI) program.

If the DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled indications, the FDA will publish a Notice of Opportunity for a hearing (NOOH) in the Federal Register concerning its proposal to withdraw approval of the drug for marketing. At that time, a manufacturer of that drug or identical, related or similar (IRS) drugs has the opportunity to request a hearing and provide FDA with documentation of the effectiveness of the drug product before a final determination is made. Drugs for which a NOOH has been published are referred to as less-than-effective (LTE) drugs. The IRS counterpart of a LTE drug is also considered as LTE.

### Effects on Mississippi Medicaid

In accordance with the Social Security Act, federal funds participation (FFP) is not available for LTE/IRS drugs for which a NOOH is issued for all labeled indications. This means that State Medicaid programs paying for LTE/IRS drugs must do so entirely with state funds. As a result, this issue is of great importance to the Mississippi Division of Medicaid.

## FDA Action on Unapproved Products, continued

Providers should be aware that a product's National Drug Code (NDC) —the unique 11 digit number that identifies the manufacturer, product, and package size— does not ensure FDA approval, since when issuing this code the FDA does not determine whether the product is legally marketed. It does not make it any easier for practitioners that many of these products may be included in widely used pharmaceutical reference materials, such as the *Physicians' Desk Reference*, and are sometimes advertised in medical journals.

Below is a table summarizing the recent actions of the FDA regarding unapproved drugs.

Ingredient	Unapproved Products	Approved Products
Guaifenesin	All timed-released products, including single and combination products	Humibid®, Mucinex®, Mucinex DM® (2 strengths), Mucinex D® (2 strengths)
Trimethobenzamide HCl	All suppository forms, including Tigan®, Trimethobenz®, Trimazole®, T- Gen® and Tebamide®	None in suppository form
Carbinoxamine	Pediatex, numerous generics	Palgic®
Quinine	Various generics	Quaalun® (limited diagnosis only)

### More Information for Providers

Each quarter, the Centers for Medicare & Medicaid Services publishes a list of LTE/IRS drugs which has been reviewed for accuracy by the FDA. This list can be found at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/desi.pdf>.

The drug labeling, or package insert, that accompanies drug products, is the most complete single source of information on a drug. Labeling for most FDA approved drugs may be found on [DRUGS @ FDA: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

You can also visit FDA's Drug Information Pathfinder, at <http://www.fda.gov/cder/Offices/DDI/pathfinder.htm>. This site provides access links to numerous categories of drug information, information about drug recalls, [drug shortages](#), [drug approvals](#), [medication guides \(patient package inserts available for some drugs\)](#), and the US National Library of Medicine's reference site, Medline Plus, which has extensive reliable information about drugs, health conditions, and health news.

### What's Next for the FDA?

The FDA has listed other drugs which are being evaluating further and are to be addressed in the future. These include, but are not limited to the following:

Pheniramine maleate	Phenobarbital
Dexbrompheniramine	Chloral hydrate
Codeine phosphate	Hydrocodone products
Oxycodone HCl 5mg	

## Medicare Part D and Medicaid: Pharmacy Benefits

On January 1, 2006 those beneficiaries enrolled in both Medicaid and Medicare, known as dual-eligible beneficiaries, began receiving prescription drug coverage through Medicare Part D. Medicaid pays the Part D premium for these beneficiaries. There are a limited number of medications that Medicare Part D will not cover, and as a result, Medicaid picks up the coverage for.

These drugs are:

- **Benzodiazepines; generic formulations only**
- **Single entity barbiturates; limited to phenobarbital and mephobarbital (Mebaral®)**
- **OTC drugs that are listed on the Medicaid OTC formulary for all beneficiaries, excluding OTC insulin products which are covered by Medicare Part D plans**
- **Prescription vitamins such as prenatal vitamins, niacin, vitamin D and K, etc.**
- **DOM covered cough products**
- **Products that have a non-Part D covered drug such as butalbital-apap or butalbital-asa combinations**

A common misconception is that Medicaid will pay for medications that a beneficiary's Part D plan will not cover or that require a prior authorization for the Part D plan. Unless the medications are one of those listed above, Medicaid will not cover them for dual eligible beneficiaries. In these situations the pharmacist should consider contacting the beneficiary and/or their provider to discuss generic or therapeutic alternatives that are on the beneficiary's Part D plan formulary.

### Medicaid is Payer of Last Resort

Another important note to remember is this: For those beneficiaries who have Medicaid and other pharmacy coverage of any type (Medicare Part D, private insurance, etc.), Medicaid is always the payer of last resort. In addition, Medicare Part D payment should be considered payment in full and is not subject to the TPL (Third Party Liability) allowance.

### Please note:

The Qualified Medicare Beneficiary (QMB) and Specified Low-Income Medicare Beneficiary (SLMB) Programs DO NOT provide drug coverage through Medicaid. These programs are designed to cover certain out-of-pocket expenses and premiums associated with Medicare, depending on the plan. For these beneficiaries Medicaid doesn't provide any drug coverage, even those products listed above.

In addition, women enrolled in the Family Planning Demonstration Waiver Program are NOT eligible for pharmacy benefits through Medicaid. These women are eligible for Medicaid coverage of family planning services only and are not eligible to receive any other Medicaid benefits. Beneficiaries in this program are issued a yellow Medicaid card to denote that they are enrolled in the Family Planning Demonstration Program.

With the recent start of a new school year, cases of conjunctivitis are likely on the rise. The following information sheet provided by the Division of Medicaid addresses the appropriate treatment of this common childhood ailment. Several additional Medicaid Prescribing Updates are available at [www.hidmsmedicaid.com](http://www.hidmsmedicaid.com).



## Mississippi Division of Medicaid

- *Conjunctivitis can be brought on by several different causes including allergies, viruses, and bacteria.*
- *The majority of cases of conjunctivitis in children are caused by adenoviruses, rather than bacteria.*
- *Conjunctivitis is generally self-limiting. Treatment should center around increasing patient comfort, reducing duration and preventing transmission.*
- *Generically-available ophthalmic antibiotics are sufficient for many cases of bacterial conjunctivitis and provide a more cost-effective alternative to more expensive brand agents.*

# Prescribing Information Update BACTERIAL CONJUNCTIVITIS

Commonly referred to as “pink eye”, conjunctivitis is characterized by itching, tearing, discharge, irritation, or foreign body sensation. There are several types of conjunctivitis, based on etiology, including allergic, mechanical (irritative), viral, and bacterial.

### Bacterial versus Viral

The majority of cases of conjunctivitis are caused by viruses, most commonly adenoviruses. Viral conjunctivitis is self-limiting and requires no therapy other than careful hand washing to minimize spread of the virus to others. According to The American Academy of Ophthalmology, bacterial conjunctivitis may also be self-limiting and not require antibiotic therapy, although this practice is not approved for children.

### Management

The treatment of conjunctivitis centers around increasing patient comfort, reducing the duration of symptoms, and preventing transmission of infection to other patients. The following table is adapted from guidelines from the American Optometric Association.

Type	Management Guidelines
Allergic	Non-preserved lubricants, cold compresses, systemic antihistamines, topical pharmaceuticals
Bacterial	Identify organism if possible Topical ophthalmic antibiotics
Viral	Cold compresses, lubricants, ocular decongestants

### Treatment Choices

There are many ophthalmic antibiotics available for the treatment of bacterial conjunctivitis. The chart below lists available agents. Although the newer fluoroquinolones may have better *in vitro* activity against common pathogens, ophthalmic formulations of antibacterial drugs achieve high concentrations in the eye that may be effective clinically even when the organisms are reported to be resistant *in vitro*.

Agent Generic (Brand Example)	Generically Available	Agent Generic (Brand Example)	Generically Available
Sulfacetamide (AK-sulf®, Bleph-10®)	Yes	Erythromycin (Ilotycin®)	Yes
Bacitracin/polymyxin B (Polysporin®)	Yes	Trimethoprim/polymyxin B (Polytrim®)	Yes
Neomycin/polymyxin B/ bacitracin (Neosporin®)	Yes	Ciprofloxacin (Ciloxan®)	Yes
Chloramphenicol (Chloromycetin®)	Yes	Gatifloxacin (Zymar®)	No
Gentamicin (Garamycin®)	Yes	Moxifloxacin (Vigamox®)	No
Tobramycin (Tobrex®)	Yes	Ofloxacin (Ocuflox®)	Yes
Bacitracin (AK-tracin®)	Yes	Levofloxacin (Quixin®)	No

### References:

- Drugs for Some Common Eye Disorders. Treatment Guidelines from the Medical Letter, Vol. 5 (Issue 53), January 2007.
- Care of the Patient with Conjunctivitis Quick Reference Guide. Optometric Clinical Practice Guideline on Care of the Patient with Conjunctivitis. American Optometric Association, St. Louis, MO.
- American Academy of Ophthalmology Corneal/External Disease Panel. Preferred Practice Pattern: Conjunctivitis. San Francisco, CA: AAO; 2003.

HEALTH INFORMATION DESIGNS



**Health Information Designs, Inc. (HID) is the contractor for Division of Medicaid Pharmacy Services' Drug Prior Authorization and Retroactive Drug Utilization Review.**

**HID Helpful Numbers**

HID Help Desk 800-355-0486  
 HID PA Fax 800-459-2135



P. O. Box 320506  
 Flowood, MS 39232-0506

PRST STD  
 U.S. Postage

Mailing Address Line 1  
 Mailing Address Line 2  
 Mailing Address Line 3  
 Mailing Address Line 4  
 Mailing Address Line 5