DHCF Current Policy
Brand Medically Necessary and
Medicaid Maximum Allowable Cost List

- **Program Description**

The Wisconsin Medicaid Maximum Allowable Cost (MAC) Program establishes maximum allowable reimbursement for generic drugs with multiple sources. The Wisconsin MAC program started in the 1970s. The Wisconsin MAC program began shortly after Wisconsin pharmacy regulations were changed to permit pharmacists to substitute, without physician authorization, the generic drug when a prescription is written for the brand name drug. Physicians can restrict substitution by indicating in their own handwriting on the prescription "brand medically necessary."

Because of MAC programs that mandate generic drug use unless the physician requires brand use, 98% of drugs available from multiple sources are dispensed generically. Most brand name drug use is for drugs with narrow therapeutic indices such as cardiac or seizure medications.

- **Generic Drug History**

Federal law allows drug developers to obtain a patent that provides exclusive rights to the developer of a drug for 20 years. Much of this 20 years is spent in research and product development. Manufacturers usually receive exclusive rights to market a product for about 10 years.

The Hatch-Waxman Act, passed in 1984, rewards the first generic drug manufacturer who challenges the validity of an existing patent on a brand name drug with a 180-day period of exclusive marketing rights for the generic drug. During this six-month period, a duopoly exists which retards significant price competition. Generally, generic manufacturers establish their prices about 25% to 30% less than the price of the brand name product. High utilization drugs have multiple manufacturers who begin marketing their drugs as soon as the 180-day generic exclusivity expires. Within six months, the price of the generic drug often drops to less than 10 percent of the brand name product.

Recently, drug manufacturers have successfully extended patents, thus delaying the introduction of equivalent generic drugs. For example, manufacturers may receive multiple patents on products that include not only the drug itself, but also drug delivery systems and drug indications. In addition, manufacturers may be granted a six-month patent extension to test and establish the efficacy and dosage of a drug for children.

- **Federal Upper Limit Program**

The federal Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) issues a drug Federal Upper Limit (FUL) list twice a year, though more commonly on an annual basis (42 CFR 447.332 and Section 1927(e) of the Social Security Act, as amended by OBRA 1993.) This list includes drugs that are available generically from at least three companies.

State payment for multiple source drugs must not exceed, in the aggregate, payment levels determined by applying to each drug entity:

- A reasonable dispensing fee (established by the State and specified in the State plan).

- An amount based on the limit per unit which CMS has determined to be equal to 150 percent applied to the lowest price listed (in package sizes of 100 units) in any of the published compendia of cost information of drugs. The listing is based on data from First Data Bank (Blue Book), Medi-Span, or the Red Book

➢ **Comparison of Federal Upper Limits and Wisconsin MAC Lists**

The federal FUL list:
- Includes 300 to 350 drugs.
- Applies only to legend drugs.
- Requires at least three generic sources for the drug.
- Uses a discount from AWP to determine prices.

The Wisconsin MAC list:
- Includes over 1,000 drugs.
- Applies to most generic legend and all over-the-counter (OTC) drugs.
- Requires a generic drug to be readily available, but not necessarily from three sources.[1]
- Reflects prices pharmacies actually pay for drugs.

Because there are only two manufacturers for the first six months of generic availability and because federal FUL regulations require three or more manufacturers, placement of a drug on the FUL is often delayed.

➢ **Wisconsin MAC Drug Selection**

The following criteria are applied in selecting a drug for establishment of a MAC price:
- Drugs must have two or more sources that are uniformly available to Wisconsin pharmacies.
- MAC prices must be at least 25% less than innovator prices.
- Drugs on the LIST must be "A" (e.g. AA, AB) rated in the FDA Orange Book.
- MAC prices are established for all covered OTC and most generic legend drugs.

➢ **Process for Establishing Wisconsin MAC Prices**

The process for establishing and reviewing MAC prices in Wisconsin on a quarterly basis includes:
- DHCF Consultant pharmacist determines actual wholesale prices to pharmacies from drug wholesalers and buying groups.
- Prices are set at approximately 10% to 25% more than the lowest acquisition price.
- New MAC lists are published quarterly.
- An appeal process assures that:
  - If more than one pharmacist provides documentation with invoices that the price paid is more than the MAC price, the MAC price is adjusted, even prior to the quarterly update.
  - If the acquisition price falls significantly, adjustments are made to the MAC price at the next quarterly update.
- Wisconsin MAC prices are, on average, approximately 65% below AWP. (The Office of the Inspector General in the Department of Health and Human Services recently reported a

range of actual acquisition cost in Wisconsin of AWP minus 54% to 72% for multi-source drugs.)