



GENERIC PHARMACEUTICAL ASSOCIATION

August 17, 2005

The Honorable Don Sundquist
Chairman
Medicaid Advisory Commission

Dear Governor Sundquist:

As Congress searches for ways to achieve greater efficiencies in the Medicaid program without undermining access to needed, quality, and affordable care, one of the few policy options that meets all of these criteria is the enhanced use of generic drugs. Because the Food and Drug Administration (FDA) has repeatedly affirmed that generic pharmaceuticals are safe and therapeutically equivalent, they serve as an essential and effective tool to constrain health costs while maintaining high quality care.

Recognizing this fact, consumers, businesses, unions and insurers have embraced the widespread use of generics. Moreover, states that have implemented “generics substitution first” policies in their Medicaid programs have moderated their unsustainable pharmaceutical cost burden—with absolutely no negative impact on quality care. In fact, based on current trends and proportional costs to savings ratios, **a one percent increase in generic drug use in Medicaid will result in federal/state savings of approximately \$500 million per year.**

Yet, some proposals for pharmaceutical reimbursement currently circulating would have the unintended consequence of severely undermining generic substitution within the program, resulting in a tremendous negative impact on the overall costs of Medicaid. We urge the Commission to, at minimum, maintain the economic incentive to dispense generics to assure the critical cost savings they provide to the system.

As the Commission executes its mandate, the Generic Pharmaceutical Association (GPhA) requests that it recommend Congress adopt the state-of-the-art generic utilization incentives described below.

Brand carve-outs for mental health drugs have proven to be expensive for the State of Florida. Two years after the state implemented a preferred drug list with a carve out for mental health drugs, analysis by state officials showed elimination of that carve out could save Florida approximately \$30 million a year.²

States that have rejected arguments by certain brand-name industry representatives advocating for brand-carve outs (anti-generic substitution) policies have achieved substantial savings without any impact on health outcomes. In fact, after a policy change in the state of Kentucky that treated an anti-psychotic drug like all other medications covered by the state, “mental health advocates said they could trace no ill effects to the decision.”³

POLICY: Require that all states transition out of their “Brand Carve-Out” (anti-generic substitution) policies.

III. PROVIDE FEDERAL INCENTIVES FOR STATE COUNTER-DETAILING PROGRAMS.

While significant progress had been made in consumer education, there is still much misinformation and misperception about the sameness and the effectiveness of generic drugs and their brand counterparts. An aggressive effort to education providers and patients can result in substantial savings.

The *Generics First* program initiated by Medco Health Services shows how significant a counter-detailing or generics education program can be. In 2002, Medco sent pharmacists to hold face-to-face clinical discussions with 1700 physicians in 10 states. In addition to the meetings, the pharmacists left patient education materials and generic samples behind that the physicians could provide to patients. The effort focused on educating the physicians on the availability, clinical benefits and economic value of generics and encouraged their use as a first line treatment.⁴

According to published reports, at least six states have experimented with similar “counter-detailing” efforts. The Wall Street Journal reported that in October 2000, a Florida “counter-detailer” visited 88 physicians who tended to prescribe brand-name anti-inflammatory drugs such as Vioxx and Celebrex. An analysis of those physicians’ prescribing habits done three months later showed a change in prescribing that was expected to save Florida \$196,000 a year.⁵

West Virginia launched a pilot “counter-detailing” program in 2002. The head of West Virginia’s Public Employee Insurance Agency predicted at the outset that a 2% increase in generic utilization (from 43% to 45%) would save his state \$1 million.⁶

² Florida Fiscal 2004-2005 Governors Recommended Appropriation Bill.

³ States Try to Limit Drugs in Medicaid but Makers Resist; New York Times; December 18, 2003.

⁴ The Bergen County Record newspaper, November 5, 2002

⁵ The Wall Street Journal, August 22, 2001

⁶ The Washington Post, August 5, 2002



IMPLEMENTATION OF EFFECTIVE MAXIMUM ALLOWABLE COST PROGRAMS WILL RESULT IN SIGNIFICANT SAVINGS FOR MEDICAID

A number of state Medicaid programs and most private third-party healthcare payors have utilized Maximum Allowable Cost (MAC) payment tools to lower the prices they pay pharmacists for all "multi-source" medications. These are categories of chemically and clinically equivalent prescriptions that have generic competition. MACs have worked to achieve hundreds of millions of dollars of savings by setting a maximum payment that states will pay for these drugs.

By capping allowable payments, MACs create incentives for pharmacists to utilize affordable generic medications. Although the Federal government has already set a Federal Upper Limit (FUL) that caps allowable federal payments for these medications, the savings achieved by MACs have proven to be much more substantial. This is because states can more frequently update the types and numbers of drugs that are available in local marketplaces, and states are likely to be more aggressive on managing payments.

CREATING NEW MAC PROGRAMS AND EXPANDING THE CURRENT ONES WILL HELP TO CONTAIN PRESCRIPTION DRUG COSTS IN THE MEDICAID PROGRAM

In recent years, the use of MAC tools for pharmacy reimbursement has increased, resulting in savings to both the federal and state portions of the Medicaid program. According to a 2003 study, the savings realized from implementing these MAC programs ranged from \$5.5 million to more than \$45 million annually per state. More than half the states currently MAC selected drug products with some states having a more aggressive program than

others. However, some of the largest states, such as New York and California, have not implemented a MAC program, leaving significant room for additional savings for the Medicaid program and the taxpayers who support it.

A 2004 report funded by the Centers for Medicare and Medicaid Services (CMS) studied five states and found that state MAC programs have achieved considerable discounts relative to FUL prices. The State of Washington estimated savings of \$7.5 million and Arkansas projected nearly \$9 million as a result of MAC programs. The Texas' MAC program was producing the largest savings, averaging a 30 percent discount relative to the FUL list price. The study made clear that all states using MACs were receiving savings and that state Medicaid programs could achieve even greater savings through more aggressive use of MAC techniques as well as more frequent publishing by the federal government of newly entering, cost effective pharmaceutical products. As Congress appropriately evaluates more efficient ways to reimburse pharmacists within the Medicaid program, the use of MACing techniques should therefore be high on the legislative agenda.

THE COMMONWEALTH OF VIRGINIA ESTIMATES IT WILL SAVE \$10 MILLION A YEAR THROUGH A NEWLY ESTABLISHED MAC PROGRAM

POLICY: EXPAND AND SUPPORT EFFECTIVE MAXIMUM ALLOWABLE COST PROGRAMS IN THE STATES TO TAKE ADVANTAGE OF EXISTING COST CONTAINMENT TOOLS.



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MASSACHUSETTS SAVED \$150 MILLION A YEAR THROUGH AN AGGRESSIVE INITIATIVE TO INCREASE GENERIC UTILIZATION

Massachusetts officials realized in 2001 that the Medicaid program was spending approximately \$10-11 million per month on brand-name drugs for which FDA-approved generic equivalent products were available. Officials at MassHealth, the Massachusetts Medicaid program, saw an opportunity for savings and implemented an aggressive program to ensure generic were dispensed instead of more expensive brand drugs.¹ New policies required prescribers to justify in writing why a brand drug should be dispensed instead of the generic if a generic form was available. As a result, the state reduced expenditures to approximately \$300,000 per month for brand drugs for which generic equivalent products were available.²

Before the implementation of this program, Massachusetts Medicaid program had a generic utilization rate of only about 47 percent. Two years later, through use of stronger substitution rules and implementation of a preferred drug list, the state has increased the percentage of generics in the program to 60 percent. In addition, Massachusetts implemented other policies, such as differential co-payments, to encourage increased generic utilization.³

	BEFORE	AFTER
Generic Utilization	47%	60%
Cost	\$10-11 million / month	\$ 300,000 / month

Savings to Massachusetts Medicaid Program \$150 million / year

Prior to implementation of the stronger rules, MassHealth had a "dispense as written" program that provided for the dispensing of generics unless a doctor wrote on the prescription pad that the brand should be dispensed. However, the state's analysis of the program found that doctors routinely ordered brand drugs even though equivalent generic alternatives were available and that the Medicaid program regularly approved the overriding of generic substitution with few questions about clinical necessity.⁴

Implementation of a Massachusetts-style generic substitution program that eliminates the unnecessary dispensing of more expensive brand-name drugs when FDA-approved generic versions are available can achieve significant savings in most states. In fact, **Dr. Mark McClellan**, Administrator of the Centers for Medicare and Medicaid Services, recently wrote, "we hope that many states will either *implement mandatory generic substitution policies for the first time or strengthen existing policies related to the use of generics.*"

POLICY: MANDATORY GENERIC SUBSTITUTION POLICIES CAN ACHIEVE SIGNIFICANT SAVINGS FOR MEDICAID. HOWEVER, SUCH PROGRAMS CAN BE INEFFECTIVE UNLESS STATES IMPLEMENT AGGRESSIVE POLICIES REQUIRING PRESCRIBERS TO PROVIDE WRITTEN JUSTIFICATION IN ORDER TO OVERRIDE GENERIC SUBSTITUTION.

ADDITIONAL INFORMATION ABOUT THE MASSACHUSETTS MODEL

Massachusetts has created forms that prescribers must use to provide justification to Medicaid officials. The forms can be found at:
http://www.mass.gov/portal/index.jsp?pageID=eohhs2terminal&L=4&L0=Home&L1=Provider&L2=Guidelines+for+Clinical+Treatment&L3=MassHealth+Drug+List&sid=Eeohhs2&b=terminalcontent&f=masshealth_provider_pharmacy_pa_forms&csid=Eeohhs2

The National Association of State Budget Officers (NASBO) has provided information on the program to all states and suggested that they consider similar programs as a tool to increase generic utilization and reduce Medicaid drug spending. NASBO provided the following formula for states to use in determining savings potential:

NASBO GENERIC SAVINGS CALCULATOR

Average Brand Claim Price	x	N	=	Y
Minus				
Average Generic Claim Price	x	N	=	Z
Potential Savings from Generics				\$\$\$\$

*N = Number of Claims for Brand Drug for which generics are available

¹ "Finding Substantial Medicaid Savings with Generic Drugs," National Association of State Budget Officers, April 7, 2005
² "Massachusetts Scores Progress in Holding Down Prescription-Drug Cost Hikes," Boston Globe, February 17, 2004
³ Presentation by MassHealth officials at a Medicare-Medicaid Symposium, May 5-6, 2004

GPhA

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⁴ "Finding Substantial Medicaid Savings with Generic Drugs," National Association of State Budget Officers, April 7, 2005