GPhA®
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.

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I. GENERIC SUBSTITUTION FIRST DISPENSING. As FDA has repeatedly made clear, therapeutically equivalent generic drugs are, by definition, chemically equivalent to their brand counterparts and provide the same quality of care as their brand counterparts. In order to get FDA approval, generics must have the same active ingredients, efficacy (bioequivalence) and safety profiles, manufacturing standards and dosage levels as the reference brands. The FDA has stated on numerous occasions that a generic drug, declared to be therapeutically equivalent, can be safely dispensed as a replacement for its brand counterpart. Accordingly, dispensing of generic drugs should be the default practice and a common, cost-effective Medicaid coverage practice. In addition, successful generic substitution first dispensing programs should require written medical justification for brand substitution by a prescriber.

In Massachusetts, Medicaid officials have taken a series of steps in the past three years that the state estimates shaved $150 million off the annual tab for drugs. A large part of the savings came from a change in a policy that required pharmacists to dispense generics first drugs unless a doctor specified that he/she wanted brand-name drugs instead. Doctors were routinely asking for brand-name drugs by writing "dispense as written," and Medicaid was paying $10 million to $11 million a month for brand-name drugs that had generic equivalents. After reviewing the situation, Massachusetts' Medicaid program put in place a tougher policy: A doctor must explain why, in writing, and get permission from the Medicaid program in order to force dispensing of a brand drug instead of its equivalent generic. Once the new policy went into effect, spending on brand-name drugs with generic equivalents dropped dramatically to $200,000 to $300,000 a month.[1] Massachusetts' Medicaid program achieved significant savings while continuing to provide high-quality care to their beneficiaries.

POLICY: Require that all states utilize default "generic substitution first" dispensing in Medicaid unless there is a written medical justification for brand substitution by a prescriber.

II. PRECLUDE BRAND CARVE-OUT (ANTI-GENERIC SUBSTITUTION) POLICIES. While many states have taken action to encourage the use of cost-effective generics, some states have instituted brand drug industry-supported practices for certain classes of products that make it extremely easy for physicians to bypass default generic drug laws and access expensive brand drugs with little or no medical justification.

The policy rationale for these provisions is based on the erroneous assumption that chemically equivalent generic drugs in certain therapeutic classes can undermine treatment outcomes of some patients. There is no scientific or medical basis for this policy nor is it consistent with FDA's determination of therapeutic equivalence. Simply stated, these brand carve-out (anti-generic substitution) policies increase state Medicaid program costs by hundreds of millions of dollars without any credible, independent evidence-based studies of better outcomes. Moreover, no such brand carve-out policies exist for traditional health insurance that is provided to non-Medicaid populations.

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[1] Tough Medicine is Paying off For State; Boston Globe; February 17, 2004

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]

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[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

Under current law, however, state counter-detailing programs are not eligible for enhanced federal Medicaid match. If counter-detailing programs were eligible for enhanced federal Medicaid match, states would be more likely to implement these programs and the generic substitution rates are likely to increase.

POLICY: Change Medicaid law to allow enhanced federal Medicaid match for state counter-detailing programs.

IV. REFORM PHARMACY REIMBURSEMENT BY SUBSTITUTING STATE-OF-THE-ART PAYMENT INCENTIVES TO INCREASE (OR AT LEAST MAINTAIN) GENERIC DRUG DISPENSING INCENTIVES. The Administration and the Congress have made clear that they wish to alter current pharmacy reimbursement policy to more accurately reflect acquisition costs of pharmaceutical products – all the while ensuring sufficient compensation to ensure access to pharmacists. In recent weeks, the Congress has increasingly indicated and wisely concluded that the substitution an Average Sales Price (ASP)-based reimbursement policy for widely used Average Wholesale Price (AWP)-based formulas falls short of desirable reform on a number of separate fronts. The ASP is subject to manipulation, does not adequately reflect pharmacy costs and actually reduces incentives for dispensing lower cost generic drugs by utilizing percentage add-ons to the base payment.

Fortunately, there are a number of sound alternatives that are either in place in a number of states or are being seriously considered. GPhA believes that any reimbursement system needs to be built on a base reimbursement which is market-based, accurately reflects acquisition costs, encourages generic drug utilization, and ensures fair and adequate reimbursement to pharmacists. Such options could include state-of-the-art Maximum Allowable Cost (MAC) approaches, which uses market pricing of three or more multi-source prescriptions marketed to cap state (and indirectly federal) financial exposure and encourage the use of generics. In states where these policies have been aggressively promoted and implemented, pharmaceutical savings has been dramatic. For example, the state of Illinois has the highest generic utilization rate (57%) in the country and employs an aggressive MAC reimbursement approach. Other alternatives could use more accurate, market-based formulas, such as "widely available market price" (WAMP) as a base payment along with a reasonable dispensing fee that ensured access to pharmacies, adequate compensation, and incentives for generics.

POLICY: Reject any ASP-based reform and substitute market-based policies (such as MACing or WAMP-based formula approaches) that accurately reflects acquisition costs, encourages generic drug utilization, and ensures fair and adequate reimbursement to pharmacists.

V. PUBLISH THE FEDERAL UPPER LIMIT (FUL) MORE FREQUENTLY. Federal Medicaid law imposes ceilings on the federal government match for payment amounts to pharmacists for the prescription drugs they dispense to Medicaid beneficiaries. The FUL is the ceiling for drugs with three or more versions. The payment ceiling for each drug is set at 150 percent of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules. The FUL is

currently published by CMS only twice a year. However, cost-effective generic versions of drugs are constantly being introduced. Publishing updates only twice a year results in an artificially high FUL because the lower cost of the newest generic version of the drug is not included in the calculation. A frequently updated FUL by the states would therefore encourage greater use of cost-effective generic drugs. With this in mind, we recommend that the FUL be revised and published no less than once per month. To ensure broader federal savings, CMS should also consider being more aggressive on enforcing federal matching rules for those states that submit costs/claims in excess of the FUL.

POLICY: Require CMS to update the FUL at least monthly in order to provide a more accurate ceiling for generic drug reimbursement.

VI. UTILIZE A ZERO CO-PAYMENT FOR GENERIC DRUGS TO CREATE AN INCENTIVE FOR DISPENSING OF LOWER COST GENERICS. Federal law allows a "nominal" co-payment for prescription drugs in the Medicaid program but it does not require co-payments. Currently states may set dispensing for Medicaid up to a maximum of $3. While some states have differential co-payments for brand and generic, a $0 co-payment for generics would provide an additional incentive for Medicaid beneficiaries to choose generic drugs when available. Lower co-payments for generic prescriptions provide consumers with an incentive to choose generics over more expensive brands resulting in lower healthcare costs for consumers, insurers and state programs. Differential co-payments are a common tool used in the private sector to encourage generic utilization. As an example, West Virginia's Public Employees Insurance Agency waived the co-payment on generic antibiotics during the first quarter of 2002 in an effort to encourage generic utilization. Although plan membership grew approximately 10% during that period, the plan experienced an increase of only 1.2% in use of brand antibiotics while generic antibiotic usage grew 10%.

POLICY: Require that states set co-payments for generic drugs at $0 to encourage Medicaid recipients to request lower cost generic equivalents over more expensive brand drugs.

The simple fact is that generic drugs drive Medicaid savings for states while providing high quality patient care. Congress should adopt aggressive generic utilization policies to maximize savings and help ensure the long-term sustainability of the Medicaid program. GPhA applauds the Commission's efforts to address the complex challenges before it and we stand ready to assist the Commission in its endeavors.

Sincerely,

Kathleen Jaeger

Kathleen Jaeger
President & CEO

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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.

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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

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