STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

NOV 14 2012

The Honorable Peter A. Hammen
Chairman
House Health and Government Operations Committee
241 House Office Bldg.
Annapolis, MD 21401-1991

Re: HB 1004 (2012) – Medical Assistance Program – Generic Drug Reimbursement Program – Report

Dear Chairman Hammen:

In response to your letter dated July 9, 2012, I am submitting the enclosed report on potential cost savings that could be achieved through the implementation of a generic drug supplemental rebate program as proposed in HB 1004 – *Medical Assistance Program – Generic Drug Reimbursement Program*. The bill did not pass, but the committee requested that the Department examine the issue and report its findings by December 1. Magellan Medicaid Administration completed an analysis of the impact of incorporating generic products into the Maryland Medicaid Preferred Drug List (PDL) and supplemental rebate program. The report presents the findings of the financial analysis requested by the committee; factors that should be considered when determining whether to include these activities in the PDL; and recommendations on this issue.

Thank you for your consideration of this information. If you have any questions or need more information on this subject, please contact Marie Grant, Director of Governmental Affairs at (410) 767-6481.

Sincerely,

Joshua M. Sharfstein, M.D.
Secretary

Enclosure

cc: Chuck Milligan
Tricia Roddy
Marie Grant
Patrick Dooley
Erin Hopwood

PETER A. HAMMEN
46th Legislative District
Baltimore City

Chair
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Operations Committee

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THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

July 9, 2012

Received

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Department of Health
and Mental Hygiene

Joshua M. Sharfstein, M.D.
Secretary
Department of Health and Mental Hygiene
201 W. Preston Street
Baltimore, Maryland 21201

Dear Secretary Sharfstein:

During the 2012 legislative session, House Bill 1004 – *Medical Assistance Program – Generic Drug Reimbursement Program* – was considered by the House Health and Government Operations Committee. The bill would have required the Department of Health and Mental Hygiene to establish a generic drug supplemental rebate program that included, for drug classes with at least two generic drug products, a solicitation of supplemental rebates from generic drug manufacturers during consideration of inclusion of their drugs on the Medicaid Preferred Drug List.

Given the potential fiscal impact of passing House Bill 1004, the Committee is requesting that the Department of Health and Mental Hygiene conduct an analysis on the potential cost savings that could be achieved through the implementation of a generic drug supplemental rebate program. Specifically, the committee is requesting that the analysis utilize data from a 12-month period and include, at a minimum: 1) the State maximum allowable cost list (SMAC) for generic drugs; and 2) the federal supply schedule generic drug price list.

Thank you for your time and consideration of this research request. The committee will be asking for a briefing on the analysis in December 2012. If you have any questions related to this request, please contact committee counsel, Erin Hopwood, at (410) 841-3770.

Sincerely,

Peter A. Hammen

Peter A. Hammen, Chair

CC: Delegate A. Wade Kach
Dr. Natalie D. Eddington, Dean, University of Maryland School of Pharmacy
Barbara Klein, University of Maryland Baltimore, Government Affairs
Marie Grant, DHMH, Governmental Affairs

Maryland Generic PDL Analysis

Introduction

Upon request by the Maryland Department of Health and Mental Hygiene, Magellan Medicaid Administration has completed an analysis of the impact of incorporating generic products into the Maryland Medicaid Preferred Drug List (PDL) and supplemental rebate program. This report presents the findings of the financial analysis requested by Delegate Hammen in his letter to Secretary Sharfstein, dated July 9, 2012; factors that should be considered when determining whether to include these activities in the PDL; and our recommendation regarding this issue.

The primary goal of the Maryland Medicaid Pharmacy Program is to provide quality, affordable care to the recipients enrolled in the program. The focus to ensure appropriate access to medications is vital to successful clinical outcomes for these members. Currently, the Maryland Medicaid Pharmacy Program utilizes a combination of Prospective Drug Utilization Review, Utilization Management, Preferred Drug List, and State Maximum Allowable Cost to manage costs while offering quality care and reliable access to medications for all recipients.

Background

The Maryland Medicaid Pharmacy Program (MMPP), determines the reimbursement amount for generic drugs (drugs with at least two manufacturers) using a "lower-of" pricing methodology.

At the time of claim adjudication, the methodology calculates and selects the lowest of:

- State Maximum Allowable Cost (SMAC),
- Estimated Acquisition Cost (EAC),
- Federal Upper Limits (FUL's), or
- Usual and Customary (U&C).

SMAC represents the ceiling price that the program is going to reimburse for generics and is determined by:

- Ascertaining the lowest cost from among the approved interchangeable multiple source products from each wholesaler that the Program has current and accurate pricing information; and
- Selecting as the SMAC the highest of the costs ascertained.

EAC is the lowest price as determined by the following criteria:

- Average Wholesale Price (AWP) minus 12%;
- Wholesale Acquisition Cost (WAC) plus 8%; or
- Direct Price (DP) plus 8%.

The Federal Upper Limits (**FULs**) represent the ceiling price that the federal government has established for generic drugs.

Usual and Customary (**U&C**) is a charge determined by the individual provider for cash paying customers[1].

When a claim for a generic drug is processed for payment, the MMPP compares the EAC, SMAC, FUL and U&C and pays the pharmacy provider the lesser of these prices. Doing so ensures that generic drugs are reimbursed at the most cost-effective rate for the state.

Financial Analysis

As requested by Delegate Hammen, an analysis was conducted using MMPP actual drug payments for SFY 2012 for generics with at least 2 manufacturers, the MMPP SMAC list and the federal supply schedule generic drug price list. The actual drug payment for generics was approximately $40 million.

Fee-For-Service Generic Claims FY 12

	All Generic Drugs	Generics Paid **with** SMAC Pricing	Generics Paid **w/out** SMAC Pricing
Total Claims	2,394,307	2,139,086	255,221
Total Amount Paid	$ 40,104,607	$ 27,956,281	$ 12,148,326

We then removed the SMAC price from the pricing methodology and re-priced the claims in order to determine the savings from the SMAC program.

Current Savings by utilizing SMAC Pricing

Number of Claims Paid with SMAC Pricing	Total Ingredient Cost* using SMAC Pricing	Total Ingredient Cost* excluding SMAC Pricing	Total Savings using SMAC Pricing
2,139,086	$ 20,425,885	$ 74,266,214	$ 53,840,329

*Ingredient Cost excludes co-pay, dispensing fee etc.

[1] Many independent and chain pharmacies offer a 30-day supply of a prescribed list of generic products, typically maintenance drugs, to their patients for $4 per prescription. Under Medicaid Policy, all providers are required to report their U&C charge for each prescription. Thus, MMPP achieves additional savings through these generic programs.

The analysis demonstrated that the **MMPP SMAC program saved the MMPP over $53.8 million in SFY 2012.** Implementing a generic supplemental rebate program will require MMPP to forego the SMAC program, which in turn will jeopardize the SMAC savings, as prices will be set based on the cost of the selected manufacturers as opposed to the inclusion of all available products.

A financial analysis was also conducted for the state of Maryland to determine potential cost savings associated with a supplemental rebate program for generics. Our analysis was based on experience in Texas where such a generic supplemental program was initiated. **Revenue generated by this initiative was demonstrated to be 0.033%** of the total generic drug spend for the period.

Estimated Savings by utilizing Generic Supplemental Rebate Program

	Total $ Generic Rx Payment	% Rebate of Total Drug Spend based on "other" state Experience	Estimated Savings ($)
Actual Expenditure with SMAC Pricing	$ 40,104,607	0.033%	$ 13,235*
Projected Expenditure without SMAC Pricing	$ 93,944,936	0.033%	$ 31,002

* Only if all of the generic prescriptions are filled with preferred generic brand

Based on actual MMPP utilization data and expenditure for SFY 2012 ($ 40M), the loss of estimated savings due to the SMAC program identified above ($ 53.8 million) and using First DataBank generic indicators, MMPP's generic drug spend in SFY 2012 would have been approximately $93.9M. Based on this expenditure, the potential annual supplemental rebate in Maryland is estimated to be approximately $31,002 annually.

This analysis does not take into consideration the costs associated with managing a supplemental rebate program for generic products. The components of managing such a program include:

- Bid solicitation
- Financial analysis
- P&T preparation
- Contract generation, execution, and evaluation
- Invoicing and reconciliation
- Prior Authorization of non-preferred drugs

Such costs would most certainly be significantly higher than the estimated supplemental rebate that the program would generate. Using the MMPP's current experience for managing the supplemental rebate and prior authorization program for branded drugs, it is estimated that the cost to manage a supplemental rebate program for generics will be between $1.5 and $2.0 million

The addition of a requirement for preferred generic manufacturers has the potential to adversely affect the State, recipients and pharmacy providers. Potential impact on each of these groups is described below.

Impact on the State

The SMAC program utilizes strategic pricing for generic products, which has offered the State significant savings while allowing pharmacies the freedom to choose which products they purchase and to maximize their own strategic business practices to ensure a positive profit margin. Implementing a generic preferred drug list will possibly eliminate the SMAC program and wipe out all the savings that it generates for MMPP.

In addition, MMPP achieves savings through the various $4 generic programs offered by many pharmacies today. MMPP's "lesser of" pricing logic defaults to a reimbursement which is the least expensive for the State. Frequently, even with the SMAC program, the calculated cost of a generic is more than $4. Therefore, the State reimburses the pharmacy at the U&C, offering additional savings to the program. By requiring the pharmacy to purchase a different brand of generic, their costs will increase and the resulting impact will require pharmacies to either limit, eliminate or increase the price for their $4 generic programs.

In scenario one: If MMPP continues **the current reimbursement methodology**, the State of Maryland would continue saving $ 53.8 million by utilizing SMAC price and avoid significant impact to the Medicaid Recipients and Pharmacy Providers as described below.

In scenario two: If MMPP implements a Generic Supplemental Rebate Program with the current reimbursement methodology **including the SMAC price**, the savings resulting from the proposed Program will be $ 13,235 and the State will incur an estimated $ 1.5 to $ 2.0 million in administrative costs and will also have a significant impact to the Medicaid Recipients and Pharmacy Providers.

In scenario three: If MMPP implements a Generic Supplemental Rebate Program with the current reimbursement methodology **without the SMAC price**, the savings resulting from the proposed Program will be $ 31,002; however MMPP will stand to loose the $ 53.8 million in SMAC price savings and will also incur the additional administrative costs estimated at $ 1.5 to $ 2.0 million and will also have a significant impact to the Medicaid Recipients and Pharmacy Providers.

Impact on Recipients

In general, patients develop a bond with their pharmacist and benefit from the face-to-face interaction achieved when receiving their prescription medications. As indicated in this analysis, there are several factors associated with preferring specified generic products that may limit or reduce the number of pharmacy providers willing to participate in the Maryland Medicaid program. By potentially limiting the number of participating pharmacies, patients could be faced with moving their prescription business to a pharmacy where they aren't comfortable asking questions to maximize their response to their medication therapy. Additionally, there could be significant access issues to participating pharmacies.

Also explained below in the section detailing how this program could impact pharmacies is the potential need for these providers to carry two different inventories; one inventory for Medicaid recipients and another for all other patients. This necessity could leave Medicaid recipients at risk for encountering an "out-of-stock" situation which would result in delayed access to care and could create other health issues while they wait for their medication to become available. Additionally, these availability issues could result in an increase in substitution of different "preferred" manufacturers. The changing of manufacturers of certain products (warfarin, phenytoin, etc.) can result in varied amounts of drug in the blood stream and adversely affect the patient's clinical outcome.

Impact on Pharmacy Providers

Pharmacy providers purchase drug products from wholesale distributors as well as directly from selected manufacturers. In both purchasing relationships, pharmacies use a variety of strategies to obtain these products at the lowest possible cost; therefore, increasing their ability to achieve a positive profit margin. These strategies include forming buying groups, negotiating for volume based discounts, and contract pricing for exclusivity agreements. As a result of these strategies, not all pharmacies pay the same price for all medications.

The inclusion of selected generic manufacturers (which may not be under contract to the pharmacy provider) on the PDL could significantly impact the pharmacy's ability to compete in the market place and could affect access to these medications for Maryland Medicaid recipients. This concern applies to all pharmacies but could be especially significant to smaller, independent pharmacies.

By limiting purchasing options to a prescribed list of manufacturers, pharmacies will be required to purchase the "preferred" manufacturers at a cost that is potentially higher than their current selections, thus driving up costs and limiting their ability and/or desire to participate in the Medicaid Program.

EPIC Pharmacies Inc. is a not-for-profit buying group available to independently owned pharmacies and includes many Maryland pharmacies in its membership. This group has a contract with one of the major generic manufacturers which offers EPIC pharmacies a "best price" for their generic products. If this particular manufacturer is not a selected "preferred" manufacturer under the Maryland Medicaid program, all of these pharmacies would incur cost increases for their generic products. In addition, most major chains also have similar agreements with their contracted manufacturers and would experience similar cost implications.

Drug shortages occur in the marketplace at a rate that is currently difficult to manage. By pushing market share to a limited number of generic manufacturers whose supply may not be able to meet the demand, these shortages could become more critical and could create access issues for Maryland Medicaid recipients.

Lastly, if pharmacies are required to purchase more costly products for their Medicaid patients, they would be required to carry two different inventories which would also drive their costs higher.

All of these factors could influence pharmacies to reconsider their business decision to participate in the Medicaid Pharmacy Program. Should Maryland experience a significant withdrawal of participating pharmacies, recipients could have significant issues getting to a provider pharmacy.

Conclusion and Recommendation

At least two states have considered initiating a program to solicit supplemental rebates for generic products. The first state, indicated in our above analysis, did implement the program as required by state legislation. The second state released a Request for Proposal (RFP) asking manufacturers to submit bids for such a program. Notices were sent to the 16 largest manufacturers of generic drugs and ten of these companies did download the RFP; however they did not receive any proposals.

Our experience has demonstrated a lack of interest for such a program on the part of the generic manufacturers. This is likely due to various factors, including the low cost of generic products, small profit margins, and the existing OBRA rebate requirements.

Maryland's expected supplemental rebate for such a program would be overshadowed by the loss of savings through the SMAC and $4 Generic programs. In addition, the costs associated with administering such a program would most certainly exceed the revenue generated by the supplemental rebate, whether the program is run internally or sourced to an outside vendor. In addition to the negative savings, a program which restricts the pharmacy's ability to negotiate purchasing agreements with generic manufacturers could place an undue burden on providers, causing them to terminate their status as Medicaid providers.

The downstream effect of all of the issues above could result in a hardship for the recipients served by the Maryland Medicaid Program.

Magellan Medicaid Administration recommends that Maryland continue their current strategy for generic pricing as this method demonstrates significant savings without compromising access to care for the members it serves.