Report on the Maximum Allowable Cost Generic Drug Reimbursement Methodology

Virginia Department of Medical Assistance Services

January 2007

TABLE OF CONTENTS

I. BACKGROUND

The 2004 General Assembly, through Item 326 WW (1) of the 2004–2006 Appropriations Act, directed the Virginia Department of Medical Assistance Services (DMAS) to implement a new pricing methodology used to reimburse pharmacies for multiple source drugs dispensed to Medicaid recipients. Specifically, the General Assembly directed DMAS to amend the Virginia Medicaid State Plan by replacing an existing drug pricing methodology, known as the Virginia Maximum Allowable Cost (VMAC) program, with a new pricing methodology that is referred to simply as the Maximum Allowable Cost (MAC) program. The General Assembly also required DMAS to report on the savings achieved through the new MAC program by January 1 of each year of the biennium. The 2006 General Assembly directed DMAS to continue the MAC program through Item 302 Y(1) of the 2006–2008 Appropriations Act (Appendix A).

The MAC drug pricing methodology, which became effective in December 2004, is applicable to multiple source drugs, which are drugs that are made by several companies and are available in both brand name and generic versions. Generic drugs contain the same active ingredients as their brand name equivalents, but are typically sold at less expensive prices. In fiscal year (FY) 2005, Virginia Medicaid spent approximately $174 million (or 28 percent) of the total $622 million in pharmacy expenditures on multiple source drugs. The purpose of the new MAC program is to set prices for multiple source drugs that more accurately reflect the true acquisition costs incurred by pharmacies than the previous VMAC program. It is expected that the more accurate MAC methodology will produce lower reimbursement prices on average which will produce savings for the Commonwealth.

This is the third annual report on the MAC program. The second annual report was submitted to the General Assembly in January 2006. Chapter I provides a brief overview of state pharmaceutical reimbursement policies and a description of both the VMAC and MAC pricing methodologies. Chapter II presents an analysis of the impact of the MAC program since December 2004, and it includes a comparison of the MAC prices against prices calculated using other pricing methodologies, the frequency with which pharmacy claims for multiple source drugs were paid at MAC prices, the change in drug payments since the MAC program was implemented, and the effect of the program on the State's pharmacy community.

Based on the analysis performed for this study, DMAS staff estimated that the MAC program has saved the State approximately $12 million since its implementation in 2004. However, it should be noted that this estimate is subject to several caveats that have made it increasingly difficult to accurately estimate the savings generated exclusively by the MAC program. These caveats are discussed in Chapter II.

A Brief Overview of State Medicaid Pharmaceutical Reimbursement Policies

In 1965, Congress created the Medicaid program through Title XIX of the Social Security Act. Medicaid is a federal-state insurance program that provides health care coverage for low-income Americans. Under federal law, state Medicaid programs are required to cover certain "mandatory" services for beneficiaries such as inpatient and outpatient hospital care, laboratory and X-ray services, and early and periodic screening, diagnosis, and treatment (EPSDT) services for children under the age of 21. Because Medicaid is a federal-state initiative, state Medicaid programs receive federal matching funds to finance the coverage of mandatory services for Medicaid recipients. Federal law also grants states the authority to cover additional "optional" services. For instance, states may provide recipients with optional benefits such as dental care, clinic services, and prescription drug coverage. States also receive federal matching funds for providing recipients with coverage of federally-approved optional benefits.

Prescription drug coverage has become an important optional benefit that all state Medicaid programs provide to their recipients. It has also been one of the fastest growing components of Medicaid spending nationally. Prescription drug coverage is a particularly important benefit for elderly and disabled recipients because they depend on prescription drugs to maintain or improve their health and well-being. Elderly and disabled recipients who are eligible for both Medicaid and Medicare are referred to as "dual eligibles". State Medicaid agencies typically incur some of their highest costs for providing drug coverage to dual eligibles because of the nature of their health conditions. However, this trend has changed due to the implementation of the Medicare Part D program that transferred drug coverage responsibility for dual eligibles from the state Medicaid programs to the federal Medicare program on January 1, 2006.[1]

Under federal Medicaid guidelines, the Centers for Medicare and Medicaid Services (CMS) is responsible for establishing maximum prices that states may pay pharmacies as reimbursement for providing prescription drugs to Medicaid recipients. These maximum prices are known as federal upper limits (FUL). The FUL represents the maximum amount that Medicaid will reimburse pharmacies for certain multiple source drugs. Prior to the Deficit Reduction Act (DRA) of 2005, the FUL was equal to 150 percent of the average wholesale price for the lowest priced version of the drug product. However, with the enactment of the DRA, the FUL is scheduled to be set at 250 percent of the average manufacturer price for multiple source drugs where the Food and Drug Administration (FDA) has rated two or more equivalent products. This change is scheduled to become effective on January 1, 2007. The federal government anticipates that this revision will produce savings for the Medicaid program because the average

[1] Because Medicare did not previously provide its beneficiaries with drug coverage, dual eligibles received this benefit through the Medicaid program. However, Medicaid drug coverage for dual eligibles ended with the implementation of the Medicare Part D program on January 1, 2006.

manufacturer price for drugs is substantially lower than the average wholesale price.

For CMS to set a FUL price for a particular drug, a sufficient number of therapeutically equivalent versions must be available from at least three manufacturers.[2] Federal guidelines allow states to reimburse pharmacies for certain drugs at rates that are lower than the federal upper limits. However, because not all drugs have FULs, states may establish reimbursement limits for non-FUL drugs using certain pricing methodologies.

About half of Virginia's Medicaid population receives services through managed care organizations (MCOs) that set their own reimbursement rates for drugs. For instance, MCOs may reimburse providers based on rates set using pricing methodologies such as average wholesale price (AWP) minus a percentage discount or a specific maximum allowable cost. For the remaining Medicaid recipients, providers are reimbursed on a fee-for-service (FFS) basis. Pharmacies dispensing multiple source drugs to FFS Medicaid recipients are paid based on the lowest of four prices calculated using the following pricing methodologies:

- Federal Upper Limit (FUL);
- Maximum Allowable Cost (MAC);
- Average Wholesale Price (AWP) minus 10.25 percent; and
- Pharmacy's usual and customary charge.

Additional information on these pricing methodologies is provided in Exhibit 1. The purpose of reimbursing pharmacies based on the lowest rate calculated using multiple methodologies is to ensure that DMAS functions as a prudent purchaser of prescription drugs.

Virginia's Maximum Allowable Cost (VMAC) Program Previously Applicable to Multiple Source Drugs

The pricing methodology that was in place from 1993 through November 2004 is referred to in this report as the Virginia Maximum Allowable Cost (VMAC) program to distinguish it from its replacement MAC program. The intent of the VMAC methodology was to produce cost savings for DMAS by calculating reimbursement rates for multiple source drugs that were lower than the rates calculated using the other methodologies. The VMAC program was based on a drug pricing methodology developed and updated by the Virginia Department of Health. DMAS did not have control of the regularity or methodology used to set VMAC prices.

[2] Under the DRA, FUL prices will be set for drugs that are available from at least two manufacturers. As a result of this change, more drugs will receive FUL prices.

Exhibit 1

Multiple Source Pricing Methodologies Used in Virginia

Federal Upper Limit (FUL): In 1987, CMS established a set of limits on payment for multiple source generic drugs, which are drugs defined as therapeutically equivalent medications produced by at least three manufacturers. CMS set the ceiling for these drugs at 150 percent of the average wholesale price for the least costly drug in the therapeutically equivalent group. This policy was developed to encourage pharmacies to substitute cheaper generic drugs for more expensive brand name drugs. The Deficit Reduction Act of 2005 has revised the FUL by setting it at 250 percent of the average manufacture price for multiple source drugs where the FDA has rated two or more equivalent products, which is a significantly lower price than the average wholesale price. This change will become effective on January 1, 2007. The federal government estimates that this change will produce approximately $3.6 billion in savings nationally through reduced payments to Medicaid pharmacy providers.

Maximum Allowable Cost (MAC): The MAC methodology resembles the federal upper limit (FUL) methodology in that it establishes maximum reimbursement amounts for equivalent groups of multiple source drugs. While basing reimbursement payments off the FUL can save states money, they can achieve additional savings by implementing a MAC program because: 1) they can include more drugs in these programs than are covered under the FUL program (not all drugs have FUL prices), and 2) they can potentially set reimbursement rates for drugs that are lower than the FUL rates.

Average Wholesale Price (AWP): The AWP is a manufacturer's published price for a drug product. Because pharmacies often purchase drugs at a percentage discount (price minus a percentage discount), states that use this methodology establish reimbursement rates by estimating a percentage discount and subtracting that number from the drug's AWP.

Usual and Customary Charge*: This charge represents the actual price that pharmacies charge cash-paying customers for prescription drugs.

***Certain government affiliated non-profit hospitals that operate pharmacies serving a high percentage of low-income patients are eligible to receive payment under the federal 340B Drug-Pricing Program, which is an additional reimbursement methodology used by DMAS. This methodology allows providers to purchase outpatient drugs at prices that are equal to or lower than the prices paid by the Medicaid program, and Virginia Medicaid reimburses at that acquisitioning cost.

The VMAC methodology distinguished multiple source drugs by the type of packaging, or whether the drug was a "unit" or "non-unit" dose drug. A unit dose is the prescribed amount of each dose in a separate package. For instance, a sealed package containing two Tylenol capsules represents a unit dose. These drugs are usually distributed in nursing homes and long-term care facilities. Non-unit dose drugs are packaged in larger containers. For instance, a

pill bottle containing 250 Tylenol capsules is a non-unit dose drug. To establish VMAC reimbursement rates for multiple source drugs, similar types of drugs were rank-ordered based on their prices. The VMAC reimbursement rate was then set at the 60th percentile for unit dose drugs and at the 75th percentile for non-unit dose drugs.

To keep up with the dynamic nature of the generic drug market, drug prices should be updated and re-calculated regularly. However, the VMAC program was not monitored and updated on a regular basis. Therefore, the VMAC prices were often higher than the prices set using other methodologies, such as AWP-10.25 percent or FUL. For example, the VMAC rate for Trimox 125mg (a non-unit dose antibiotic) was $0.03640 per 100 pills in 2004, which was higher than its FUL rate of $0.02010 per 100 pills. Consequently, DMAS rarely reimbursed pharmacies for multiple source drugs based on their VMAC rates.

Virginia's New Maximum Allowable Cost (MAC) Program for Multiple Source Drugs

The 2004 General Assembly directed DMAS to replace the VMAC methodology through the 2004-2006 Appropriations Act. The 2006 General Assembly directed DMAS to continue the MAC program through the 2006-2008 Appropriations Act. The new MAC program differs from the VMAC program in both its administration and pricing methodology. In particular, DMAS contracted with a third party vendor, Optima Health, to develop the MAC program and to administer its daily operations. Optima Health is a regional non-profit organization that provides both commercial and Medicaid health care services and coverage in Virginia and North Carolina. The MAC program became operational on December 1, 2004. As a result, prescriptions for multiple source drugs are now paid based on the new MAC rates when they are the lowest of all possible rates calculated using the MAC methodology as compared to the other pricing methodologies. The program is designed to produce cost savings for DMAS by reducing reimbursement to pharmacies for multiple source drugs. Optima Health also continuously monitors market conditions to assure that pharmacies receive sufficient reimbursement for drugs paid using the MAC methodology.

The revised MAC price for any given drug is no less than 110 percent for the lowest-published wholesale acquisition cost (WAC) for products widely available for purchase in Virginia and included in national pricing compendia (e.g., publications produced by private companies that include descriptive and price information on drugs approved by the Food and Drug Administration). The MAC prices are established based on market prices for each drug in accordance with certain criteria. Examples of these criteria include the requirement that at least three different suppliers are able to supply the drug and that pharmacies are able to purchase sufficient quantities of the drug. The drugs must also be

listed as therapeutically and pharmaceutically equivalent on the Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication. To ensure that pharmacies stay informed of the MAC program, DMAS posts a list of MAC rates via its website (www.dmas.virginia.gov) under the "Pharmacy Services" section. While MAC prices are updated weekly, the MAC list on the DMAS website is updated monthly, contains a column with the effective MAC price dates, and denotes changes among monthly reports.

Figure 1 provides an example of how MAC prices are established. Optima Health first identifies multiple source drugs that are available from at least three manufacturers. Once the products have been identified, Optima selects the drug with the lowest WAC and multiples that price by 1.1. To give pharmacies the ability to purchase drugs from multiple vendors, Optima also selects the WAC with the second lowest price and multiplies it by 1.06. This addresses situations where the lowest priced product has a large gap between the second lowest priced product and gives pharmacies more choices in product selection. Then the MAC price is set for the drug based on the higher of the two rates derived from this process. It should be noted that MAC prices are set for multiple source brand name drugs and their generic equivalents. However, DMAS' mandatory generic drug program requires that generic drugs be dispensed instead of the more costly brand name products, unless overridden by the prescribing physician. As of September 2006, there were 42,542 drugs covered under the MAC program. The number of drugs in the MAC program will increase over time because Optima Health is responsible for monitoring the drug market on a daily basis and adding new drugs as they become eligible for the MAC program based on the formula.

Figure 1

Methodology Used to Set a MAC Price for a Multiple Source Drug

Lisinopril 30 mg Tablet	**WAC Rate**				**MAC Rate**
Version with Highest WAC	$0.9038				
Version with 2nd Lowest WAC	$0.6030	X	106%	=	$0.6392
Version with Lowest WAC	**$0.6025**	X	110%	=	**$0.6628**

The MAC rate for this drug is set at $0.6628, which is the highest of the two possible reimbursement rates.

Note: Lisinopril is a cardiovascular drug.

II. IMPACT OF THE MAC PROGRAM

To evaluate the impact of the MAC program, DMAS staff compared drug prices calculated using the MAC methodology against other pricing methodologies, analyzed pharmacy claims data to determine the frequency at which claims were paid at MAC rates, estimated the change in drug payments since the program's implementation, and reviewed the program's effect on Virginia's pharmacy community.

Based on this analysis, DMAS staff found that the MAC methodology calculates reimbursement rates for most multiple source drugs that are lower than the prices calculated using the other methodologies. DMAS staff also found that a majority of claims for drugs covered under the MAC program have been paid at the MAC rates since December 2004. In addition, DMAS staff found that the MAC program has resulted in approximately $12 million in savings for the State since its implementation date. However, the savings estimate may not be entirely attributable to the MAC program because the mandatory generic drug program and the preferred drug list (PDL) program, which are other pharmacy cost reduction strategies, were implemented concurrently and cover many of the same drugs. Moreover, DMAS experienced substantial reductions in its pharmacy expenditures during FY 2006 due to the expansion of the managed care program and the implementation of the Medicare Part D program which may further skew the savings estimate. Finally, DMAS staff found that the impact of the program on Virginia's pharmacy community appears to have been minimal. Additional details on the analyses performed by DMAS staff are provided in the sections below.

The MAC Program Produces Prices that are Lower than the Prices Produced by Other Methodologies for Most Multiple Source Drugs

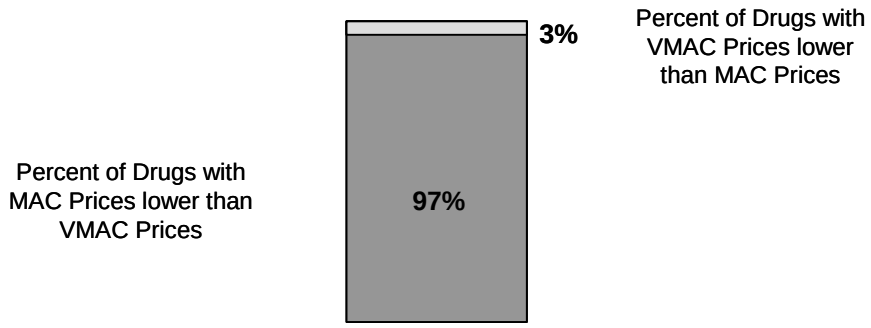
As previously discussed, the VMAC methodology often established reimbursement rates for multiple source drugs that were higher than the rates calculated using other pricing methodologies, such as AWP-10.25 percent or FUL. Consequently, DMAS rarely reimbursed pharmacy providers for multiple source drugs based on the VMAC rates. To correct this issue, the General Assembly directed DMAS to revise the VMAC methodology.

To determine if the new MAC methodology addressed this issue, DMAS staff compared MAC prices for multiple source drugs against prices that were calculated using the VMAC, AWP-10.25 percent, and FUL methodologies. The new MAC methodology should usually calculate reimbursement prices that are lower than the prices generated using the other methodologies. The results of the price comparison are reported in Figure 2.

Figure 2

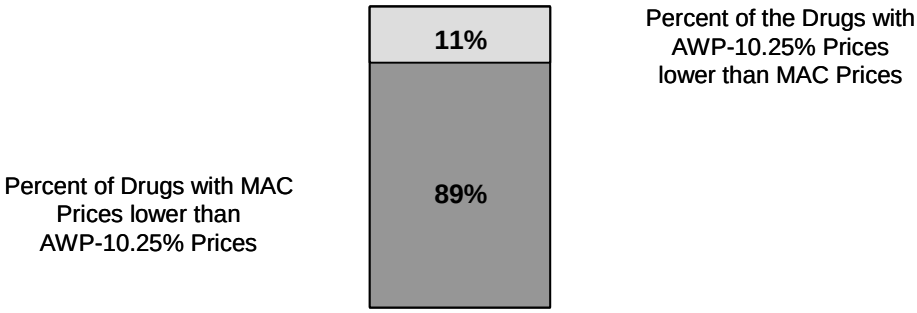
Comparison of VMAC and MAC Prices for Drugs Covered Under Both Programs

(N = 25,863)*



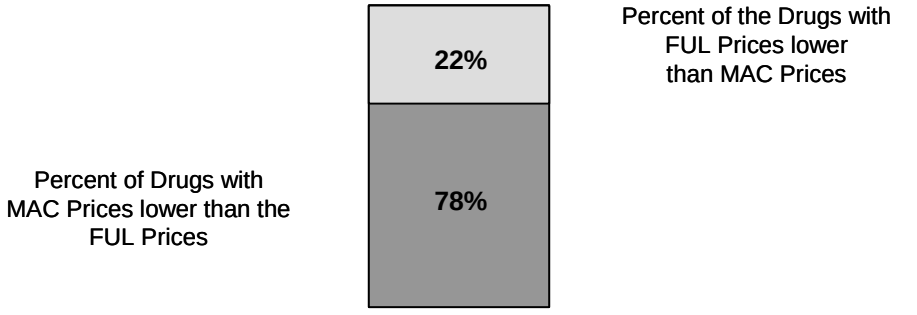
Comparison of Average Wholesale Price (AWP) – 10.25% and MAC Prices for Drugs Covered Under the Current MAC Program

(N = 42,542)*



Comparison of Federal Upper Limit (FUL) and MAC Prices for Drugs Covered Under the Current MAC Program**

(N = 25,379)*



*Sample sizes vary because of differences in the number of drugs that have prices set using the different drug pricing methodologies. This information is current as of September 2006.
**With the enactment of the revised 250 percent FUL on January 1, 2007, it is anticipated that the FUL methodology will generate reimbursement prices that are lower than those generated by the MAC program.
Source: DMAS staff analysis of MAC drug data.

As can be seen from this information, the MAC methodology generated reimbursement rates for most multiple source drugs that were lower than the rates calculated using the other methodologies. For instance, of the 25,863 drugs that were covered under both the VMAC and MAC programs, 97 percent had MAC prices that were lower than the VMAC rates. Approximately 89 percent of the 42,542 drugs covered under the MAC program had MAC prices that were lower than the AWP-10.25 percent prices, and of the 25,379 MAC drugs that had FUL prices, about 78 percent had MAC prices that were lower than the FUL prices. This information suggests that the MAC methodology is producing some savings for the State by generating reimbursement prices for most multiple source drugs that are lower than the prices calculated using other methodologies. However, it should be noted that the MAC methodology may actually produce reimbursement rates that are higher than the FUL once the FUL methodology for multiple source drugs is revised to calculate rates based on 250 percent of the average manufacturer price as stipulated in the Deficit Reduction Act of 2005.

A Majority of Claims for MAC Drugs Have Been Paid at the MAC Price Since the Implementation of the Program

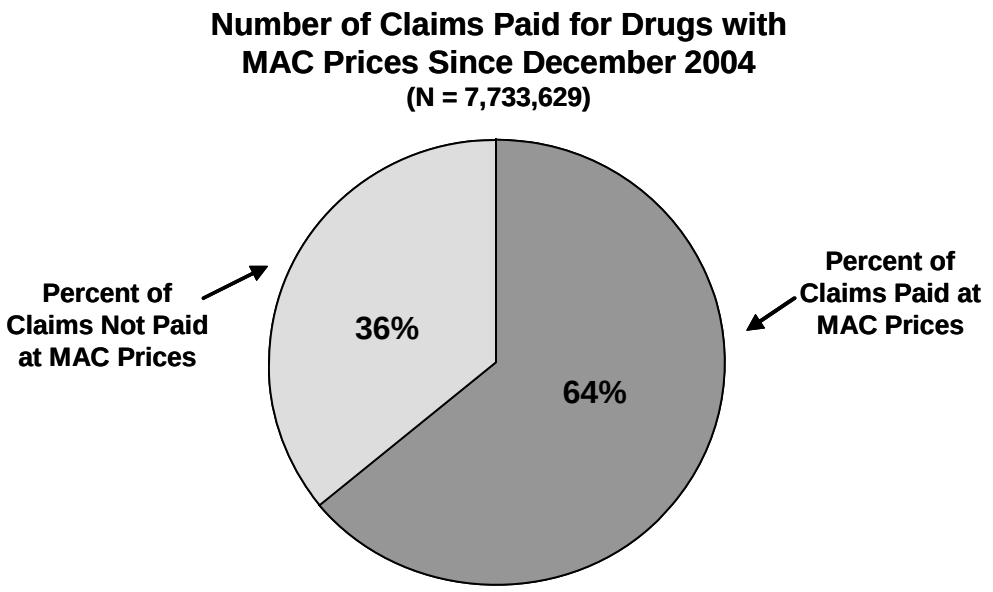
As part of the analysis performed for the MAC program's third annual report, DMAS staff analyzed the frequency at which MAC rates were used to reimburse pharmacies for providing multiple source drugs to FFS Medicaid recipients. The results of the analysis are presented in Figure 3. This information illustrates the percentage of claims paid at MAC prices between December 2004 and September 2006. As shown, DMAS received 7.7 million claims for drugs that had a MAC price. Of those claims, 64 percent were paid at the MAC price during the 22 month time period. The remaining 36 percent were paid at one of the other pricing methodologies. This information further suggests that the MAC program is producing savings for the State by generating reimbursement rates that are lower than the other methodologies.

Payments for Multiple Source Drugs Have Decreased Since the Implementation of the MAC Program

In order to estimate the cost savings of the MAC program, DMAS staff analyzed claims data for the 25,863 drugs that were covered under both the VMAC and MAC programs between July 2003 and September 2006 by comparing actual drug expenditures to forecasted amounts using a baseline prior to the implementation of the MAC program. Based on this analysis, DMAS staff estimated that the MAC program has saved the State approximately $12.0 million since December 2004.[3] It should be noted, however, that this estimate more accurately represents cost avoidance than cost savings. Cost avoidance refers

[3] Because this cost estimate is cumulative, it includes the $8.2 million savings estimate that DMAS reported in the MAC program's second annual report completed in January 2006.

Figure 3



Source: DMAS staff analysis of VMAC and MAC drug data for the December 2004 to September 2006 time period.

to the elimination of a future cost, while cost savings refers to the elimination of a present cost. This distinction is important because cost savings implies that additional funds are available in the DMAS budget since the agency saved money by reimbursing pharmacies at the lower MAC rates for multiple-source drugs covered under the program. However, the DMAS budget and forecast already reflect the savings produced by the MAC program by way of lower projected costs.

In addition, there are three caveats to the $12 million estimate that should be noted because they may influence the estimate's accuracy (i.e., the caveats may cause the $12 million estimate to be either underestimated or overestimated). First, approximately 29 percent of the 25,863 MAC drugs used for this analysis are covered under the preferred drug list (PDL) program, which was implemented on January 1, 2004 as part of a larger effort by DMAS to reduce prescription drug costs. Under the PDL program, a formulary was established for a number of therapeutic drug classes. Many of the manufacturers whose products are included in the PDL program agreed to discount their products to the State through supplemental rebates. This allowed DMAS to generate substantial savings in the prescription drug program. Second, the estimated savings of the MAC program may be influenced by the mandatory generic drug program, which was implemented on September 1, 2004. Under this program, pharmacies are required to fill all prescriptions with generic drugs unless overridden by the prescribing physicians. Third, DMAS experienced a

substantial reduction of approximately 60 percent in its pharmacy expenditures due to the expansion of the State's managed care program and the implementation of the federal government's Medicare Part D program that both occurred in FY 2006.[4] The MCO expansion and the Part D program resulted in the removal of approximately 141,000 fee-for-service recipients from DMAS' pharmacy program. As a result, the $12.0 million estimate may not be directly attributed in its totality to the MAC program due to the influence of these other programs.

The Impact of the Revised MAC Program on Virginia's Pharmacy Community Has Been Minimal

The intent of the MAC program is to reduce overall Medicaid drug expenditures, while reimbursing pharmacies fairly based on accurate generic drug costs. The implementation of the revised MAC program may reduce profits for some pharmacies that sell a substantial amount of generic and multiple source drugs or because less expensive drugs are not accessible to the pharmacy. As a result, DMAS has established a dispute resolution process to allow pharmacy providers the opportunity to challenge inaccurate MAC prices. In an effort to be as proactive as possible, the dispute resolution process was implemented on November 1, 2004, which was one month prior to the start of the MAC program. In conjunction with this effort, DMAS also published an advanced price list to pharmacy providers so they could identify any potential issues with the new MAC rates.

The impact of the MAC program on the pharmacy community appears to have been minimal. In fact, there have only been two formal disputes lodged against a MAC price since December 2004 which were resolved by Optima Health. In addition, neither Optima Health nor DMAS have received any complaints from the pharmacy community concerning the MAC program. These findings may be attributable to the fact that pharmacy providers are not penalized (i.e., reimbursed below acquisition costs) for dispensing more expensive brand name drugs (as stipulated by the prescribing physicians) for patients in lieu of less expensive generic substitutes that are covered under the MAC program.

Conclusion

Based on the analysis performed for this report, the revised MAC program appears to be producing some savings for the State because: 1) the program is calculating reimbursement rates for most multiple source drugs that are lower than the prices calculated using other pricing methodologies; 2) a majority of the claims for drugs covered under the program have been paid at MAC rates since December 2004; and 3) the program generated an estimated $12 million in savings since its implementation; however, this amount is subject to three

[4] DMAS has stopped providing drug coverage to approximately 101,000 dual eligible beneficiaries since January 2006 as a result of Medicare Part D program.

caveats discussed earlier in the report. In addition, the impact of the program on the State's pharmacy community appears to have been minimal.

Given the multiple changes that have either occurred or are scheduled to occur to the Medicaid prescription drug program, it is increasingly difficult to directly attribute the savings generated by the MAC program. However, the program is clearly part of the reduction in pharmacy costs that are reflected in the Medicaid budget forecast, and should continue as one of the pricing methodologies used for reimbursing pharmacies for multiple source generic drugs. Because of the impact of multiple pharmacy reforms, the General Assembly may wish to consider eliminating this reporting requirement.

APPENDIX A

2006 – 2008 Virginia Acts of Assembly

Y.1. The Department of Medical Assistance Services shall amend the State Plan for Medical Assistance to modify the reimbursement methodology used to reimburse for generic drug products. The new methodology shall reimburse for the product cost based on a Maximum Allowable Cost list to be established by the department. Such amendments shall be effective within 280 days or less from the enactment of this act.

2. In developing the maximum allowable cost (MAC) reimbursement rate for generic pharmaceuticals, the department shall: (i) publish the factors used to set state MAC rates, including the identity of the reference product used to set the MAC rate; the GCN number of the reference product; the factor by which the MAC rate exceeds the reference product price, which shall be not less than 110 percent of the lowest-published wholesale acquisition cost for products widely available for purchase in the state, and included in national pricing compendia; and the identity and date of the published compendia used to determine the reference product and set the MAC rate; (ii) identify three different suppliers that are able to supply the product and from whom pharmacies are able to purchase sufficient quantities of the drug. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the FDA's most recent version of the "Orange Book"; (iii) identify that the use of a MAC rate is lower than the Federal Upper Limit (FUL) for the drug, or the development of a MAC rate that does not have a FUL will not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program; and (iv) distribute the list of state MAC rates to pharmacy providers in a timely manner prior to the implementation of MAC rates and subsequent modifications.

3. The department shall: (i) review and update the list of MAC rates at least quarterly; (ii) implement and maintain a procedure to eliminate products from the list, or modify MAC rates, consistent with changes in the marketplace; and (iii) provide an administrative appeals procedure to allow a dispensing provider to contest a listed MAC rate.

4. The department shall report on savings achieved through the implementation of the Maximum Allowable Cost rates for generic pharmacy products in the Medicaid pharmacy program to the Chairmen of the House Appropriations and Senate Finance Committees, the Joint Commission on Health Care, and the Department of Planning and Budget by January 1 of each year.