

**Report on the Maximum Allowable Cost
Generic Drug Reimbursement Methodology**



Virginia Department of Medical Assistance Services

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I. BACKGROUND

The 2004 General Assembly 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, Item 326 WW (1) of the 2004-2006 Appropriations Act (Appendix A) required DMAS to amend the Virginia Medicaid State Plan to replace 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 Appropriations Act also required DMAS to report to the General Assembly by January 1 of each year on the savings achieved through the new MAC program.

The new MAC 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 sold at less expensive prices. In FY 2004, Virginia Medicaid spent approximately \$160 million (or 28 percent) of the total \$573 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 second annual report on the MAC program. The first report was submitted to the General Assembly in January 2005. 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 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.

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 optional benefits.

Prescription drug coverage has become an important optional benefit that all state Medicaid programs provide to their recipients. In fact, the prescription drug benefit is one of the fastest growing components of Medicaid spending nationally and one of the program’s most widely utilized services. It is a particularly important benefit for elderly and disabled recipients who depend on prescription drugs to maintain or improve their health and well-being. All state Medicaid programs cover prescription drugs, though some place limits on either eligibility groups or the types of drugs that are covered. For example, Virginia Medicaid does not cover prescription drugs that are used for fertility or cosmetic purposes.

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. The 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, and it is equal to 150 percent of the lowest priced version of the drug product.

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. 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 (VMAC or MAC);
- Average Wholesale Price (AWP) minus 10.25 percent; and

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 that are produced by at least three manufacturers. CMS set the ceiling for these drugs at 150 percent of 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.

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 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.

- 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.

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, which is 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

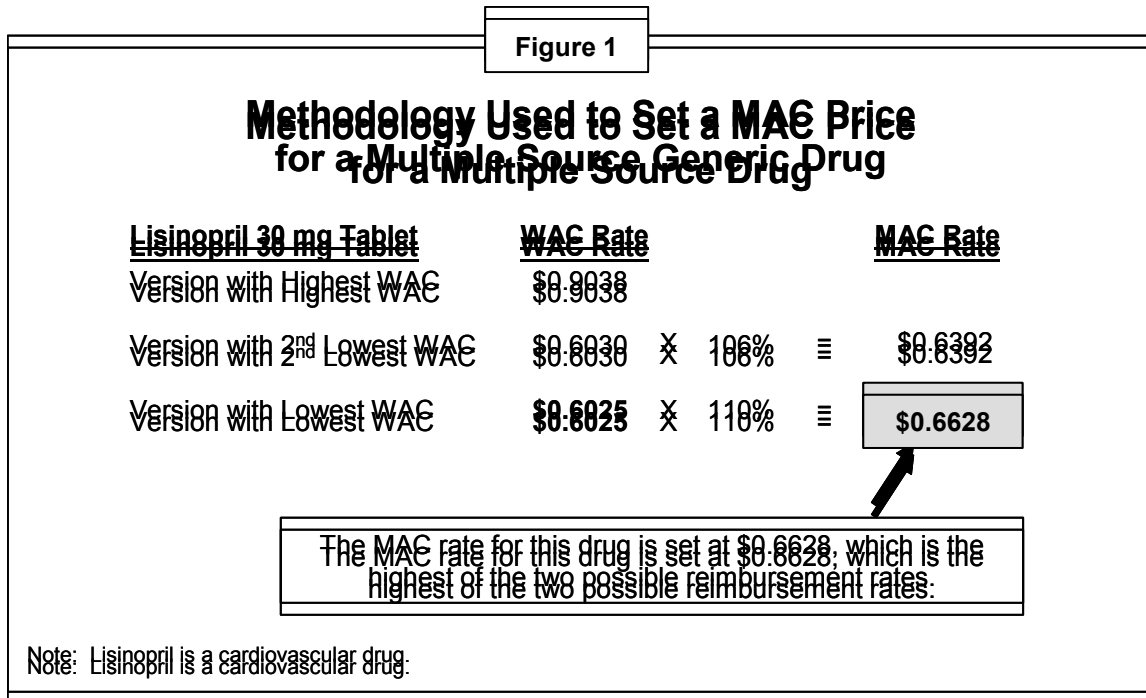
The 2004 General Assembly directed DMAS to replace the VMAC methodology through the 2004-2006 Appropriations Act. The new drug pricing methodology is now referred to simply as the Maximum Allowable Cost (MAC) program. The MAC program differs from VMAC in both its administration and its pricing methodology. In July 2004, 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 commercial and Medicaid health care services and coverage in Virginia and North Carolina. The MAC program became operational on December 1, 2004 at which time prescriptions for multiple source drugs were paid based on the new MAC rates when they are the lowest of all possible rates calculated using 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 FDA approved drugs). The MAC prices are established based on market prices for each drug in accordance with three parameters:

1. There must be at least three different suppliers that can supply the drug and pharmacies must be able to purchase sufficient quantities of the product. The drugs that are considered must be listed as therapeutically and pharmaceutically equivalent on the Food and Drug Administration’s “Approved Drug Products with Therapeutic Equivalence Evaluations” publication.
2. If the drug has a FUL, the pricing methodology will determine whether the MAC rate is lower than the drug’s FUL rate. If the MAC rate is higher than the FUL, then the pharmacy will be reimbursed using the FUL rate.
3. The list of MAC rates is available to pharmacies via the DMAS website (www.dmas.virginia.gov) under the “Pharmacy Services” section. The MAC list is updated monthly and contains a column with the effective MAC price dates.

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 multiplies 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 physicians. As of October 2005, there were 34,433 drugs covered under the MAC program. The number of drugs in the MAC program will increase over time because Optima Health is now 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.

II. IMPACT OF THE MAC PROGRAM

To evaluate the impact of the MAC program, DMAS policy 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 generated approximately \$8 million in savings for the State since its implementation date. However, this cost savings 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. 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 policy 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

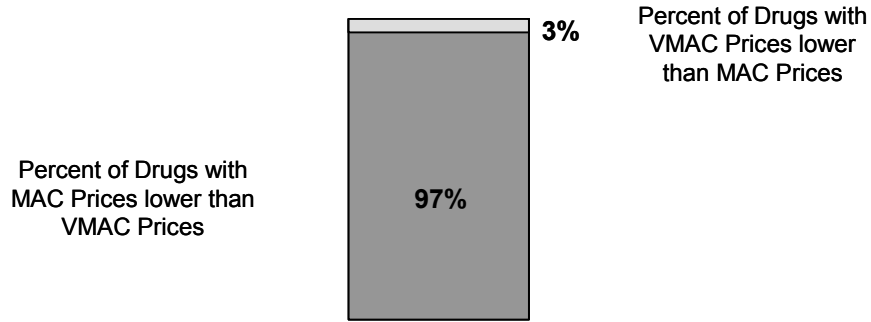
As previously discussed, the VMAC methodology often established reimbursement rates for multiple source drugs that were higher than the rates calculated using other pricing methodologies, such as AWP-10.25 percent or FUL. Consequently, DMAS rarely reimbursed pharmacy providers for multiple source drugs 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.

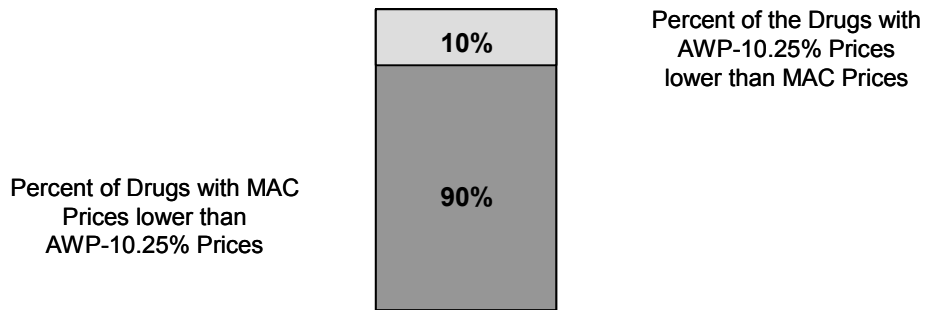
As can be seen from this information, the MAC methodology generated reimbursement rates for most multiple source drugs that were lower than the rates calculated using the other methodologies. For instance, of the 24,956 drugs that were covered under both the VMAC and MAC programs, 97 percent had MAC prices that were lower than the VMAC rates. Moreover, of the 34,313

Figure 2

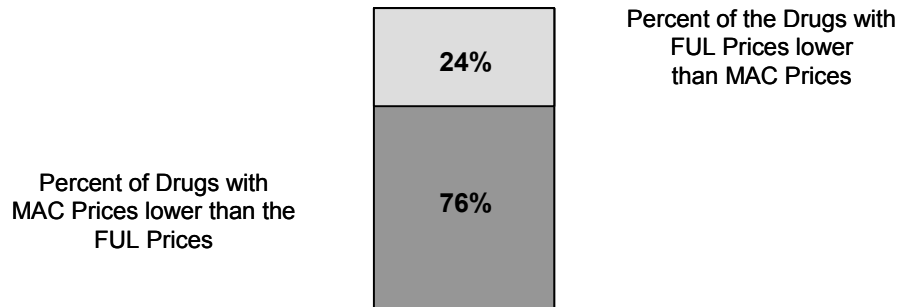
**Comparison of VMAC and MAC Prices for Drugs Covered Under Both Programs
(N = 24,956)**



**Comparison of Average Wholesale Price (AWP) – 10.25% and MAC Prices for Drugs Covered Under the Current MAC Program
(N = 34,313)**



**Comparison of Federal Upper Limit (FUL) and MAC Prices for Drugs Covered Under the Current MAC Program
(N = 12,279)**

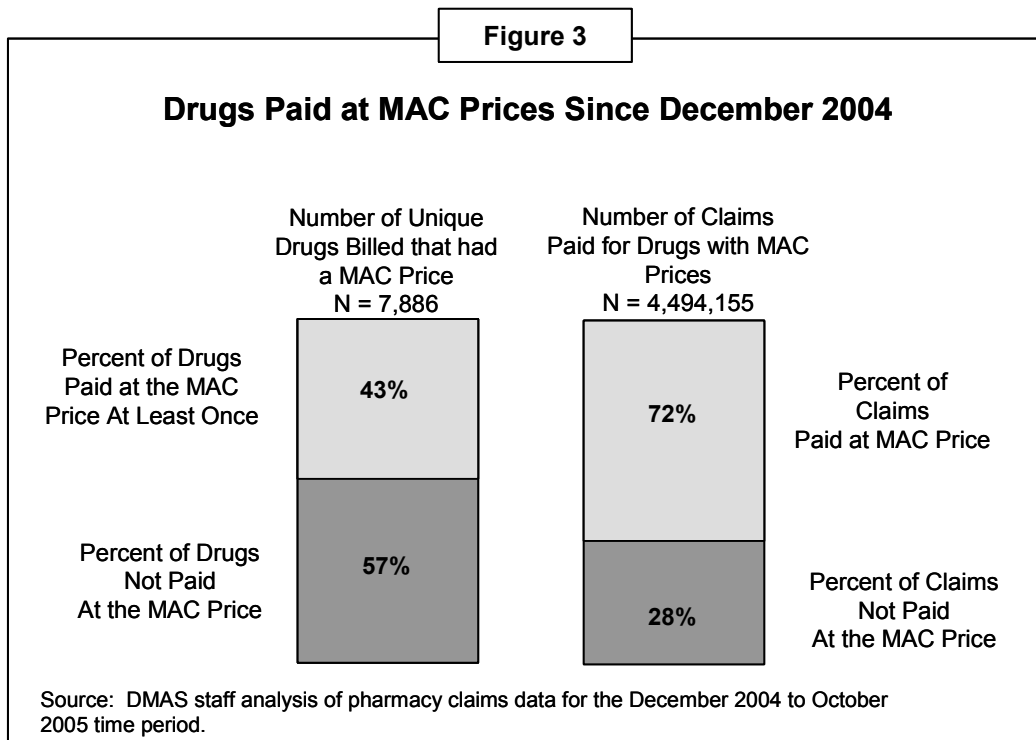


Note: Sample sizes vary because of differences in the number of drugs that have prices set using the different drug pricing methodologies. This information is current as of October 2005.
Source: DMAS staff analysis of MAC drug data.

MAC drugs that had AWP-10.25 percent prices, approximately 90 percent had MAC prices that were lower than their AWP prices, and of the 12,279 MAC drugs that had FUL prices, about 76 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.

A Higher Percentage of Drug Claims are Paid at the MAC Price than Were Paid at the Previous VMAC Price

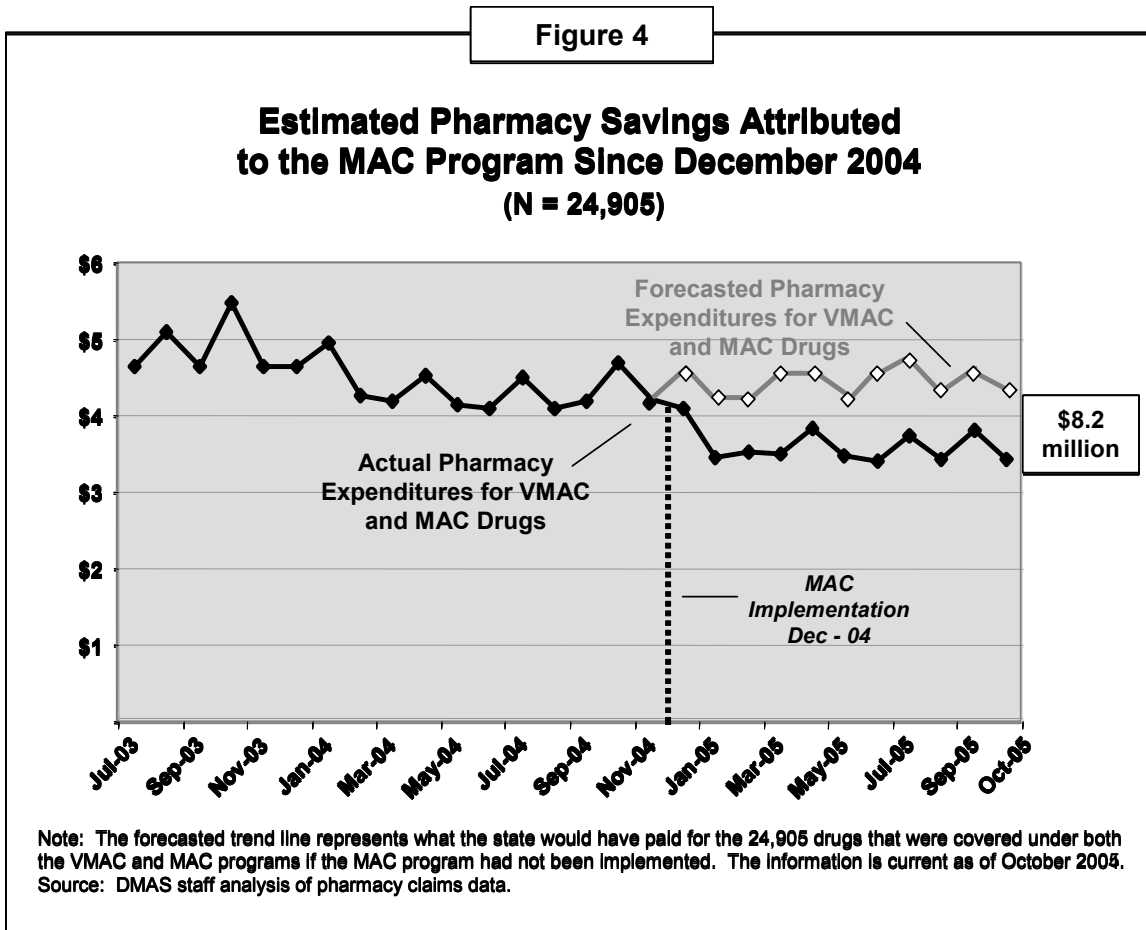
In the MAC program’s first annual report, DMAS policy staff analyzed the frequency at which VMAC rates were used to reimburse pharmacies for providing multiple source drugs to FFS Medicaid recipients. The analysis found that only seven percent of the 4.5 million claims that DMAS received for VMAC drugs during FY 2004 were paid at the VMAC rates. DMAS staff performed the same analysis for the second annual evaluation. The results of the analysis are presented in Figure 3. This information illustrates the percentage of drugs billed that had a MAC price as well as the number of claims paid at MAC prices between December 2004 and October 2005. As shown, DMAS received claims for 7,886 unique drugs that had a MAC price. Of those drugs, 43 percent were paid at least once during the 11 month time period at the MAC price. Looking more specifically at the claims, 72 percent of the 4.5 million claims for drugs that had a MAC price were paid at the MAC rate. The remaining 28 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 24,905 drugs that were covered under both the VMAC and MAC programs between July 2003 and October 2005 by comparing actual drug expenditures to forecasted amounts using a baseline prior to the implementation of the MAC program.¹ The results are presented in Figure 4. Based on this information, DMAS policy staff estimates that the MAC program has saved the State approximately \$8.2 million since December 2004.



¹ The cost savings analysis was actually performed in September 2005. At the time of the analysis, 24,905 drugs were covered under both the VMAC and MAC programs. However, this number increased to 24,956 drugs in October 2005.

However, there are three caveats to this cost estimate. First, the estimate is based on a short term projection rather than a long term projection. Consequently, the projection could either underestimate or overestimate the actual cost savings of the program. Data covering several years should be analyzed before a more accurate cost estimate can be presented. Second, 30 percent of the 24,905 MAC drugs 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. In fact, DMAS staff estimated that the PDL program has saved the State almost \$35.2 million since June 2004. Third, the estimated savings of the MAC program may be influenced by the mandatory generic 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. As a result, the \$8.2 million cost estimate may not be directly attributed in its totality to the MAC program because it does not account for the influence of the PDL program or the mandatory generic drug program.

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.

The impact of the MAC program on the pharmacy community appears to have been minimal. Since December 2004, there has only been one formal dispute lodged against a MAC price and the dispute was resolved by Optima Health. Moreover, none of the 47 phone calls that have been placed to the MAC call center that is managed by Optima Health have involved drug price disputes. In addition, Optima Health nor DMAS has received no e-mails from the pharmacy community concerning the MAC program.

Conclusion

Based on the analysis performed for this report, the revised MAC program appears to be saving the State money 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 \$8 million in savings since its implementation; however, this amount is subject to three caveats discussed earlier in the report. In addition, the impact of the program on the State's pharmacy community appears to have been minimal.

APPENDIX A

2004 – 2006 Virginia Acts of the Assembly

WW.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 MAC rates in the Medicaid pharmacy program to the Chairmen of the House Appropriations and Senate Finance Committees, and the Joint Commission on Health Care by January 1 of each year.