Maximum Allowable Cost Program
Reimbursement Methodology for Generic Drugs

Department of Medical Assistance Services

January 1, 2005

Introduction

The 2004 General Assembly adopted language in the 2004 – 2006 Appropriation Act directing the Virginia Department of Medical Assistance Services (DMAS) to modify the methodology used to reimburse pharmacies for providing generic drugs to Medicaid recipients. The mandate (Appendix A) requires DMAS to amend the State Plan to replace an existing pricing methodology, known as the Virginia Maximum Allowable Cost (VMAC) program, with a new pricing methodology referred to simply as Maximum Allowable Cost (MAC). The Appropriation Act also requires DMAS to report to the General Assembly by January 1 of each year on the savings achieved through the new MAC program.

This is the program's first annual program status and cost savings report. It provides a brief overview of state pharmaceutical reimbursement policies and discusses both the previous and new reimbursement methodologies, and reviews the potential impact the revised methodology may have on the State's pharmacy community. Because the new MAC program began in December 2004, the actual cost savings achieved through the program will not be measurable until the next cost savings report, which will be presented in January 2006.

An Overview of State Pharmaceutical Reimbursement Policies

Federal law allows states to provide prescription drug benefits to their Medicaid recipients as an optional benefit. This service provides individuals who otherwise may be unable to obtain necessary but expensive drug therapy, with access to a broad range of prescription drugs. All states have chosen to cover prescription drugs, though some place limits on either eligibility groups or types of drugs covered. For example, Virginia does not cover prescription drugs used for fertility or cosmetic purposes.

Medicaid prescription drug coverage is becoming one of the fastest growing health care expenditures in the United States. For example, Medicaid drug spending increased nationally 194 percent from $48.2 billion to $141.8 billion between 1992 and 2001. Many states have become concerned about escalating drug costs due to resulting pressures on their budgets. In response, the Centers for Medicaid and Medicare Services (CMS), which is the federal agency within the Department of Health and Human Services that is responsible for directing the Medicaid and Medicare programs, established guidelines allowing states to implement certain drug cost reduction strategies. Examples of these strategies include authorizing states to limit reimbursement payments to pharmacies for providing prescription drugs to Medicaid recipients, and allowing states to require pharmacies to provide recipients with less costly generic drugs instead of brand name drugs.

A brand name drug is an innovator drug that holds a patent to prevent other manufactures from copying the product. It is usually available from a single manufacturer. A multiple-source generic drug is a copy of a brand name drug that contains the same active ingredients, but is usually made by several companies and marketed at less expensive prices. In Virginia, Medicaid requires that prescriptions for multiple-source drugs be filled with a generic unless the physician indicates that the brand name product is necessary.

Under federal Medicaid guidelines, CMS is responsible for establishing maximum prices that pharmacies receive 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 may reimburse pharmacies for certain multiple-source generic drugs, and it is equal to 150 percent of the lowest priced version of the drug product. For a drug to receive a FUL, 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 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. Examples of pricing methodologies that many states may use include average wholesale acquisition price (AWP) minus a percentage discount, the usual and customary charge, and the maximum allowable cost (MAC). A description of each methodology is shown below:

- The average wholesale price (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.

- The usual and customary charge represents the actual price that pharmacies charge cash-paying customers for prescription drugs.

- The Maximum Allowable Cost (MAC) methodology resembles the FUL methodology in that it establishes maximum reimbursement amounts for equivalent groups of multiple-source generic 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, and 2) they can set reimbursement rates for drugs that are lower than the FUL rates. Forty-five states currently have MAC programs. According to the U.S. Department of Health and Human Services, states can achieve substantial savings by implementing MAC programs.

The Previous Virginia Maximum Allowable Cost Reimbursement Program

Prior to December 1, 2004, DMAS reimbursed pharmacies based on the lowest of the following pricing methodologies:

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

The purpose of using the lowest of multiple methodologies was to ensure that DMAS functioned as a prudent purchaser of prescription drugs. Often, however, DMAS reimbursed pharmacies at much higher rates due to limitations with the VMAC program.

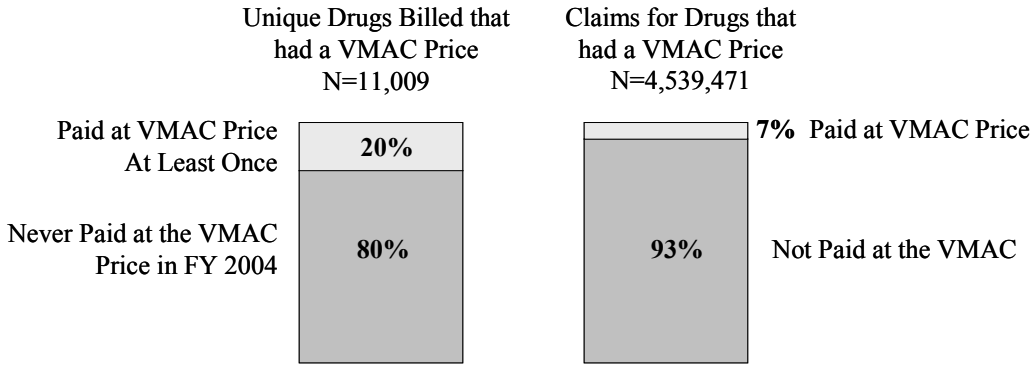
VMAC, which was established in 1993 as a cost saving measure, calculated reimbursement rates for generic drugs that were lower than the FUL rates. VMAC was based on a methodology developed by the Virginia Department of Health, which established reimbursement amounts separately for "unit" and "non-unit" dose drugs, which are distinctions related to how a drug is packaged. A unit dose is the prescribed amount of each dose in a separate package. For example, a sealed package containing two Tylenol capsules represents a unit dose. These are most often distributed in nursing homes and long-term care facilities. Non-unit dose drugs are those packaged in larger containers. For example, a pill bottle containing 250 Tylenol capsules is a non-unit dose.

The VMAC methodology established the price for unit dose drugs at the 60^{th} percentile and the price for non-unit dose drugs at the 75^{th} percentile. However, the VMAC prices did not represent the lowest reimbursement rates because the methodology did not have a point of reference that set the price at a competitive point. Moreover, the generic market is extremely dynamic and requires daily monitoring for changes and adjustments. As a result, the VMAC rates were often higher than the FUL rates. For example, the VMAC rate for Trimox 125mg (a non-unit dose antibiotic) was $0.03640, which is higher than its FUL rate of $0.02010.

Figure 1 illustrates that the VMAC rates were rarely used to reimburse claims. As shown, in FY 2004, DMAS received claims for 11,009 unique drugs that had a VMAC price on file. Of those drugs, 20 percent were paid at least once during that year at the VMAC price. Looking more specifically at the claims, only seven percent of the 4.5 million claims for drugs that had a VMAC price were paid at that price during FY 2004. The remaining 93 percent were paid using one of the other pricing methodologies described above, such as the FUL rate. Had the VMAC rates been more competitive, they would have been lower

Figure 1

Drugs Paid at the VMAC Prices in FY 2004



Source: DMAS staff analysis of claims data.

than the other rates, and DMAS would have experienced cost savings from paying at the lower rate.

The Revised Maximum Allowable Cost Program

To address this issue, the 2004 General Assembly directed DMAS to revise the VMAC methodology through Item 326 WW (1) of the 2004-2006 Appropriation Act. The revised methodology is now known simply as the Maximum Allowable Cost (MAC) program. DMAS contracted with Sentara-Optima in the fall of 2004 through a procurement process to revise the MAC methodology and to administer the MAC program. The State Plan amendment has been approved by CMS and the emergency regulations have been approved. The revised program became operational on December 1, 2004.

The revised MAC price for any given generic drug shall be no less than 110 percent of the lowest-published wholesale acquisition cost (WAC) for products widely available for purchase in Virginia and included in national pricing compendia. The MAC prices will be established based on market prices for each drug in accordance with the following parameters:

1. There must be at least three different suppliers that are able to supply the drug and from which pharmacies can purchase sufficient quantities of the product. The drugs that are considered must be listed as therapeutically and pharmaceutically equivalent on the FDA's most recent version of the "Orange Book," which is a list of approved drug products.

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, then the lower price will be paid.

3. The list of MAC rates will be available to pharmacies via the DMAS website at www.dmas.virginia.gov under the "Pharmacy Services" section. The MAC list will be updated monthly and will contain a column with the effective MAC price dates.

4. DMAS will publish the factors used to set MAC reimbursement rates, including:

   - the identity of the reference product used to set the MAC rate;
   - the generic code number (GCN) of the reference product;
   - the difference by which the MAC rate exceeds the reference product price, which will be no less than 110 percent of the lowest-published wholesale acquisition cost (WAC); and
   - the identity and date of the published compendia used to determine the reference product and set the MAC rates.

Figure 2 provides an example of how MAC prices are established. Sentara-Optima first identifies multiple-source generic drugs that are available from at least three manufacturers. Once the products have been identified, Sentara-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, Sentara-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. It then sets the MAC for the generic drug based on the higher of the two rates derived from this process. There are 29,642 drugs that currently have MAC prices.

Figure 2

Example of How a MAC Price is Established for a Multiple Source Generic Drug

Ibuprofen 800 mg Tablet	WAC Rate				MAC Rate
Version with Lowest WAC*	**$0.04312**	X	110%	=	**$0.04743**
Version with 2nd Lowest WAC	**$0.05210**	X	106%	=	**$0.05523**

The MAC rate for this drug is set at $0.05523, which is the highest of the two possible reimbursement rates.

* WAC rate for the lowest WAC was unavailable so .04312 is an example of what it could be.

Impact of the Revised MAC Program on Virginia's Pharmacy Community

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 pharmacies that sell a substantial amount of generic and multiple-source drugs. Thus, the pharmacy community may express some concerns about the MAC program.

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 – one month prior to the start of the program. A MAC Medicaid Memo was also distributed to pharmacy providers 45 days prior to the start of the program to inform them about the new pricing methodology and to allow them the opportunity to comment.

The dispute resolution process consists of three methods to handle disputes. Pharmacists can either use a Fax Form, Call or email Sentara-Optima. Pharmacists will be notified of the receipt of their dispute resolution within one business day, and a decision will be made within three business days. The pharmacy provider will either receive notice stating that the drug product can be obtained from a manufacturer at or below the MAC price, or the provider will be reimbursed accordingly based on the results of the review. The key to DMAS maintaining a positive relationship with the State's pharmacy community is to maintain a fair, expeditious, and equitable process for resolving reimbursement disputes.

In addition, the DMAS Pharmacy unit has worked proactively with the Virginia Pharmacists Association (VPhA) to address specific pricing issues with the current MAC list. For example, VPhA sent a proposed MAC list to selected providers in the independent, chain, and nursing home settings for feedback on the appropriateness of the established prices. Of the approximately 800 drugs on the proposed list, providers challenged MAC prices for 17 drugs. Of these, 10 drugs were found to have unfair prices, which were subsequently revised.

Savings Attributable to the Revised Virginia Maximum Allowable Cost Program

The 2004-2006 Appropriation Act requires DMAS to report to the General Assembly by January 1 of each year on the savings achieved by the revised MAC program. However, because the program only became operational in December 2004, DMAS has not yet been able to measure savings attributable to the program. Once DMAS has collected 12 months worth of claims data from the revised MAC program, staff will calculate the program's actual annual savings and report this information to the General Assembly in the second annual report on January 1, 2006.

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.